PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Cosentyx® 75 mg solution for injection

Solution for injection in a pre-filled syringe
for subcutaneous injection

Active ingredient:
Each pre-filled Cosentyx syringe contains 75 mg secukinumab in 0.5 ml of the solution.

Inactive and allergenic ingredients in the preparation: see section 6 "Further information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Cosentyx is intended for the treatment of the following inflammatory diseases:

- Plaque psoriasis:
  Cosentyx is intended for the treatment of moderate to severe plaque psoriasis in adolescents and children from the age of 6 and above who are candidates for systemic therapy.
- Juvenile idiopathic arthritis (JIA), which includes enthesitis-related arthritis (ERA) and juvenile psoriatic arthritis (JPsA): Cosentyx, alone or in combination with a medicine called methotrexate, is indicated for the treatment of active JIA in patients 6 years of age and older whose disease has responded inadequately to, or who cannot tolerate, conventional therapy.

Therapeutic group: Interleukin (IL) inhibitors.

The active ingredient in Cosentyx is secukinumab, a monoclonal antibody which belongs to a group of preparations called interleukin (IL) inhibitors. The medicine works by neutralizing the activity of a protein called IL-17A, which is present at increased levels in diseases such as psoriasis, psoriatic arthritis and axial spondyloarthritis.

Plaque Psoriasis
Cosentyx is a medicine used to treat the skin for the condition of plaque psoriasis, which causes inflammation affecting the skin. Cosentyx reduces the inflammation and other symptoms of the disease. Cosentyx is used to treat adolescents and children over 6 years of age with moderate to severe plaque psoriasis.

The benefit you (or your child) will gain from using Cosentyx for plaque psoriasis will manifest by an improvement that will lead to skin clearance and reduction of your symptoms, such as scaling, itching and pain.

Juvenile idiopathic arthritis, which includes enthesitis-related arthritis and juvenile psoriatic arthritis
Consentyx is a medicine used in patients aged 6 years and above to treat juvenile idiopathic arthritis (JIA), which includes enthesitis-related arthritis (ERA) and juvenile psoriatic arthritis (JPsA). These conditions are inflammatory diseases that affect the joints and the areas where the tendons connect to the bones.

The benefit you (or your child) will gain when using Cosentyx for enthesitis-related arthritis (ERA) and juvenile psoriatic arthritis (JPsA) will involve a reduction of symptoms of the disease and improvement of your physical function (or your child's physical function).

2. BEFORE USING THE MEDICINE

Do not use the medicine if:
- **you (or your child) are sensitive (allergic)** to secukinumab, or to any of the additional ingredients contained in the medicine (listed in section 6 "Further information"). If you think you (or your child) may be allergic, refer to the doctor for advice before using Cosentyx.
- **you (or your child) have an active infection** that your doctor considers significant.

Special warnings regarding use of the medicine
Before treatment with Cosentyx, tell the doctor or nurse if any of the following conditions apply to you:
- If you (or your child) currently have an infection.
- If you (or your child) suffer from long-term or repeated infections.
- If you (or your child) have tuberculosis.
- If you (or your child) ever had an allergic reaction to latex.
- If you (or your child) have an inflammatory disease affecting your gut, called Crohn's disease.
- If you (or your child) have an inflammation of the large intestine, called ulcerative colitis.
- If you (or your child) had a recent vaccination or if you (or your child) will receive a vaccination during treatment with Cosentyx.
- If you (or your child) are receiving any other treatment for psoriasis, such as another immunosuppressant or phototherapy with ultraviolet (UV) light.

Inflammatory bowel disease (Crohn's disease or ulcerative colitis)
Stop using Cosentyx and tell your doctor or seek medical help immediately if you (or your child) notice abdominal cramps and pains, diarrhea, weight loss, blood in the stool or any other sign of a bowel problem.

Look out for infections and allergic reactions
Cosentyx may cause serious side effects, including infections and allergic reactions. You must look out for signs of these conditions if you (or your child) are taking Cosentyx.
Stop using Cosentyx and tell the doctor or seek medical help immediately if you (or your child) experience any of the signs indicating a possible serious infection or an allergic reaction. Such signs are listed under "Serious side effects" in section 4.

Children and adolescents
Cosentyx is not intended for children under 6 years of age with plaque psoriasis since the preparation was not tested in this age group.

Cosentyx is not intended for children under 6 years of age with juvenile idiopathic arthritis (JIA), which includes enthesitis-related arthritis (ERA) and juvenile psoriatic arthritis (JPsA).

Cosentyx is not intended for children and adolescents under 18 years of age for treatment of other indications since the preparation was not tested in this age group.

Drug interactions
If you (or your child) are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.
Especially inform the doctor or pharmacist:
- if you (or your child) has recently had or if you (or your child) are going to have a vaccination. You or your child should avoid receiving certain types of vaccines (live vaccines) while using Cosentyx.

Pregnancy, breastfeeding and fertility
- It is preferable to avoid use of Cosentyx during pregnancy. There is no information regarding the effect of the medicine in pregnant women. If you (or your child) are a woman of childbearing potential, it is recommended to avoid becoming pregnant by using adequate contraception while using Cosentyx and for at least 20 weeks after the last Cosentyx dose.
  Tell your doctor if you or your child is pregnant, if you think you or your child may be pregnant or if you (or your child) are planning a pregnancy.
- Tell your doctor if you or your child is breastfeeding or planning to breastfeed. You and your doctor will decide if you should breastfeed or use Cosentyx. You (or your child) should not do both. After using Cosentyx, do not breastfeed for at least 20 weeks after the last Cosentyx dose.

Driving and operating machinery
Cosentyx is not expected to affect your ability to drive or operate machinery.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor, nurse or pharmacist if you are uncertain regarding the dosage and treatment regimen of the preparation. The dosage and treatment regimen will be determined by the doctor only.
Cosentyx is injected under the skin (an injection called subcutaneous). You and your doctor should decide if, after proper training, you should inject Cosentyx yourself or a caregiver should give the injection.
It is important not to try to inject yourself until you have been trained by your doctor, nurse or pharmacist.
For detailed instructions on how to inject Cosentyx, see "Instructions for use of Cosentyx 75 mg solution for injection in a pre-filled syringe" at the end of this leaflet.

Treatment duration
The doctor will decide how much Cosentyx you (or your child) need and for how long.

Plaque psoriasis (children 6 years of age and above)
The recommended dose is dependent on weight as follows:
- weight below 25 kg: the recommended dose is 75 mg by subcutaneous injection.
- weight above 25 kg and below 50 kg: the recommended dose is 75 mg by subcutaneous injection.
- weight 50 kg and above: the recommended dose is 150 mg by subcutaneous injection. The doctor may increase the dose to 300 mg.

Each 75 mg dose is given as one 75 mg injection. Other forms/strengths are available for injection of a 150 mg dose.
After the first dose, you (or your child) will receive additional weekly injections in weeks 1, 2, 3 and 4 and then injections once per month.

Juvenile idiopathic arthritis (JIA) (enthesitis-related arthritis (ERA) and juvenile psoriatic arthritis (JPsA))
The recommended dose is dependent on weight as follows:
- weight below 50 kg: the recommended dose is 75 mg by subcutaneous injection.
- weight 50 kg and above: the recommended dose is 150 mg by subcutaneous injection.

Each 75 mg dose is given as one 75 mg injection. Other forms/strengths are available for injection of a 150 mg dose.
After the first dose, you (or your child) will receive additional weekly injections in weeks 1, 2, 3 and 4 and then injections once per month.

Cosentyx is for long-term treatment. The doctor will regularly monitor your (or your child's) condition to check that the treatment is having the desired effect.

Do not exceed the recommended dose.

If you took a higher Cosentyx dosage than required
If you (or your child) took an overdose or if the dose was given sooner than scheduled by the doctor's prescription, or if a child has accidentally swallowed the medicine or injected it into himself, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to inject Cosentyx
If you forgot to inject a dose of Cosentyx at the designated time, inject the next dose as soon as you (or your child) remember. Then talk to the doctor to discuss when you should inject the next dose.

Adhere to the treatment regimen as recommended by the doctor.

If you stop using Cosentyx
It is not dangerous to stop using Cosentyx. However, if you discontinue, the psoriasis symptoms from which you (or your child) suffered may come back.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Cosentyx may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Serious side effects
- Stop using Cosentyx and inform the doctor or seek medical help immediately if you (or your child) suffer from any of the following side effects:
  Signs of **a possibly serious infection** may include:
  - fever, flu-like symptoms, night sweats.
  - feeling tired or short of breath, cough which does not go away.
  - warm, red and painful skin, or a painful skin rash with blisters.
  - burning sensation when passing urine.

  Signs of **a serious allergic reaction** may include:
  - difficulty breathing or swallowing.
  - low blood pressure, which may cause dizziness or light-headedness.
  - swelling of the face, lips, tongue or throat.
  - severe itching of the skin, with a red rash or raised bumps.

Your doctor will decide if and when you (or your child) can restart the treatment.

Other side effects
Most of the side effects mentioned below are mild to moderate. If these side effects become severe, please refer to the doctor, pharmacist or nurse.

Very common side effects (effects that occur in more than 1 user in 10):
- upper respiratory tract infections with symptoms such as sore throat and stuffy nose (nasopharyngitis, rhinitis)

Common side effects (effects that occur in up to 1-10 users in 100):
- cold sores (oral herpes)
- diarrhea
- runny nose (rhinorrhea)
- headache
- nausea
- fatigue

Uncommon side effects (effects that occur in 1-10 users in 1,000):
- oral thrush (oral candidiasis)
- signs of low levels of white blood cells, such as fever, sore throat or mouth ulcers due to infections (neutropenia)
- infection of the external ear (otitis externa)
- discharge from the eye with itching, redness and swelling (conjunctivitis)
- itchy rash (urticaria)
- lower respiratory tract infections
- abdominal cramps and pains, diarrhea, weight loss or blood in the stool (signs of bowel problems)
- small, itchy blisters on the palms of hands, soles of feet and tips of the fingers and toes (dyshidrotic eczema)
- athlete's foot

Rare side effects (effects that occur in 1-10 users in 10,000):
- severe allergic reaction with anaphylactic shock
- redness and peeling of skin over a large area of the body, which may be itchy or painful (exfoliative dermatitis)
- inflammation of small blood vessels, which may lead to a skin rash with small red or purple bumps (vasculitis)

Side effects of unknown frequency (effects whose frequency has not yet been determined):
- fungal infection of the skin and mucous membranes (including *Candida* [a type of fungus] of the esophagus)
- painful swelling and skin ulceration (pyoderma gangrenosum)

If a side effect occurs, if one of the side effects worsens or if you (or your child) suffer from a side effect not mentioned in the leaflet, consult the doctor.

Reporting of side effects
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package or on the label of the pre-filled syringe. The expiry date refers to the last day of that month.
- Do not use if the liquid contains easily visible particles, if it is cloudy or is distinctly brown.

Storage conditions: Store Cosentyx in the original box to protect it from light. Store in the refrigerator between 2°C and 8°C. Do not freeze. Do not shake.
If necessary, Cosentyx can be stored outside of the refrigerator for a single period of up to 4 days at room temperature, but not above 30°C.

Cosentyx is intended for single use only.
Do not throw away medicines via wastewater or household waste. Consult the pharmacist on how to dispose of medicines that are no longer in use. These measures will help to protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
Water for injection, Trehalose dihydrate, L-histidine/histidine hydrochloride monohydrate, L-methionine and Polysorbate 80 low peroxide quality.

What the medicine looks like and the contents of the package:
Cosentyx solution for injection is a clear liquid. Its color can vary from colorless to slightly yellow.
Each package contains 1 or 3 pre-filled syringes (not all package sizes may be marketed).

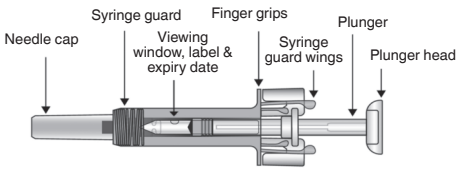
Registration Holder and Importer and its address: Novartis Israel Ltd., P.O.B 7126, Tel Aviv.

Revised in August 2023 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 154-20-34342

Instructions for use of Cosentyx 75 mg solution for injection in a pre-filled syringe
Read all the way through these instructions before injecting. It is important not to try to inject yourself or a person in your care until you have been trained by the doctor, nurse or pharmacist. The box contains Cosentyx pre-filled syringe(s), individually sealed in an opaque, plastic blister.

Cosentyx pre-filled syringe



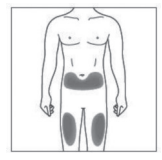
After the medicine has been injected, the syringe guard will be activated in order to cover the needle. This is intended to protect healthcare professionals, patients who self-inject doctor-prescribed medicines, and individuals who assist self-injecting patients from needlestick injuries.

Additional supplies you need for your injection:
- Alcohol swab.
- Cotton ball or gauze.
- Sharps disposal container.

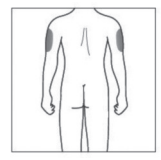
Important safety information
Caution: Keep Cosentyx pre-filled syringes out of the reach and sight of children.
1. The needle cap of the syringe may contain dry rubber (latex); persons sensitive to this substance should avoid handling it.
2. Do not open the seal of the outer box until you are ready to use the medicine.
3. Do not use the medicine if either the safety seal on the outer box or the seal of the blister is broken, as it may not be safe for you to use.
4. Do not use the syringe if it fell on a hard surface or if it fell after removal of the needle cap.
5. Never leave the syringe lying around where others might tamper with it.
6. Do not shake the syringe.
7. Be careful not to touch the syringe guard wings before use. By touching them, the syringe guard may be activated too early.
8. Do not remove the needle cap until just before the injection.
9. The syringe cannot be re-used. Dispose of the used syringe immediately after use in a sharps disposal container.

Storage of the Cosentyx pre-filled syringe
1. Store the medicine in its original outer box to protect it from light. Store in the refrigerator between 2°C and 8°C. **Do not freeze.**
2. Remember to take the syringe out of the refrigerator and allow it to reach room temperature before preparing it for injection (15-30 minutes).
3. Do not use the Cosentyx pre-filled syringe after the expiry date indicated on the outer box (exp. date) or syringe label. If it has expired, return the pack to the pharmacy.

The injection site
The injection site is the place on the body where you are going to use the syringe.
- The recommended site is the front of your thighs. You may also use the lower abdomen, but not the area 5 cm around the navel.

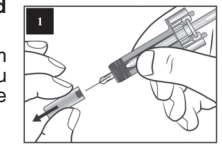


- Choose a different site each time you give yourself an injection.
- Do not inject into areas where the skin is tender, bruised, red, scaly or hard. Avoid areas with scars or stretch marks.
- If a caregiver is giving you the injection, the outer upper arms may also be used.

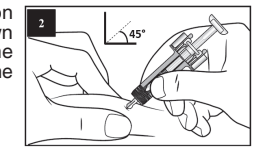


Preparing the Cosentyx pre-filled syringe
1. Take the box containing the syringe out of the refrigerator and leave it **unopened** for about 15-30 minutes so that it reaches room temperature.
2. When you are ready to use the syringe, wash your hands thoroughly with water and soap.
3. Clean the injection site with an alcohol swab.
4. Remove the syringe from the outer box and also take it out of the blister.
5. Inspect the syringe. The liquid must be clear. Its color may vary from colorless to slightly yellow. You may see a small air bubble; this is normal. **Do not use** the solution if it contains easily visible particles, is cloudy or is brown. **Do not use** the preparation if the syringe is broken. In all these cases, return the product pack to the pharmacy.

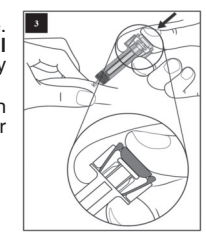
How to use the Cosentyx pre-filled syringe



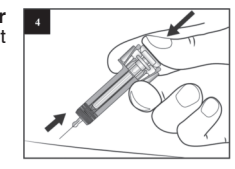
Carefully remove the needle cap from the syringe. Discard the needle cap. You may see a drop of liquid at the end of the needle. This is normal.



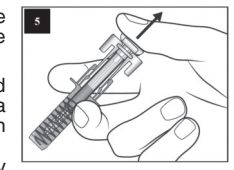
Gently pinch the skin at the injection site and insert the needle as shown in the figure. Push the needle all the way in at a 45° angle to ensure that the medicine can be fully administered.



Hold the syringe as shown in the figure. **Slowly** depress the plunger **as far as it will go,** so that the plunger head is completely between the syringe guard wings.
Keep the plunger pressed fully down while you hold the syringe in place for 5 seconds.



Continue depressing the plunger while you carefully pull the needle out of the injection site.



Slowly release the plunger and allow the syringe guard to automatically cover the exposed needle.

There may be a small amount of blood at the injection site. You can press a cotton ball or gauze over the injection site and hold it for 10 seconds.
Do not rub the injection site. You may cover the injection site with an adhesive bandage if needed.

Disposal instructions

Dispose of the used syringe in a sharps disposal container (closable, puncture-resistant container).
For the safety and health of you and others, used needles and syringes must **never** be re-used.

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Cosentyx® 150 mg solution for injection

Solution for injection in a pre-filled pen (SensoReady®-pen) *for subcutaneous injection*

Active ingredient:

Each pre-filled Cosentyx pen (SensoReady-pen) contains 150 mg secukinumab in 1 ml of solution.

Inactive and allergenic ingredients in the preparation: see section 6 "Further Information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Cosentyx is intended for the treatment of the following inflammatory diseases:

- Plaque psoriasis:
  Cosentyx is intended for the treatment of moderate to severe plaque psoriasis in adults, adolescents and children 6 years of age and older who are candidates for systemic therapy.
- Hidradenitis suppurativa (HS):
  Cosentyx is intended to treat moderate to severe active hidradenitis suppurativa (acne inversa), in adults whose response to conventional systemic treatment is insufficient.
- Psoriatic arthritis:
  Treatment with Cosentyx or combination therapy of Cosentyx together with a medicine called methotrexate (MTX) is intended for the treatment of active psoriatic arthritis in adults when the response to previous treatment with a DMARD-type medicine (disease-modifying anti-rheumatic drug) was inadequate.
- Axial spondyloarthritis, including ankylosing spondylitis (radiographic axial spondyloarthritis) and non-radiographic axial spondyloarthritis:
  Cosentyx is intended for the treatment of active ankylosing spondilitis in adults when the response to previous conventional (routine) treatment was inadequate.
  Cosentyx is indicated for the treatment of active non-radiographic axial spondyloarthritis, with signs of infection manifesting by increased levels of C-reactive protein (CRP) and/or evidence in magnetic resonance imaging (MRI) after an inadequate response to treatment with nonsteroidal antiinflammatory drugs (NSAIDs).
- Juvenile idiopathic arthritis (JIA), including enthesitis-related arthritis (ERA) and juvenile psoriatic arthritis (JPsA): Cosentyx, alone or in combination with a medicine called methotrexate, is indicated for the treatment of active juvenile psoriatic arthritis (JIA) in patients 6 years of age and older who respond inadequately to, or who cannot tolerate, conventional therapy.

Therapeutic group: Interleukin (IL) Inhibitors.

The active ingredient in Cosentyx is secukinumab, a monoclonal antibody which belongs to a group of preparations called interleukin (IL) inhibitors. The medicine works by neutralizing the activity of a protein called IL-17A, which is present at increased levels in diseases such as psoriasis, psoriatic arthritis and axial spondyloarthritis.

Plaque psoriasis

Consentyx is a medicine used as a treatment of the skin for the condition of plaque psoriasis, which causes inflammation affecting the skin. Cosentyx reduces the inflammation and other symptoms of the disease. Cosentyx is used to treat adults, adolescents and children 6 years of age and older with moderate to severe plaque psoriasis.

Using Cosentyx in plaque psoriasis will benefit you by leading to improvement of skin clearance and reducing your symptoms, such as scaling, itching and pain.

Hidradenitis suppurativa (HS)

Cosentyx is used to treat a condition called hidradenitis suppurativa, also sometimes called acne inversa or Verneuil's disease. This condition is a chronic and painful inflammatory skin disease, and its symptoms may include tender nodules (lumps) and abscesses (boils) that may leak pus. This condition commonly affects specific areas of the skin, such as: under the breasts, the armpits, inner thighs, groin and buttocks. Scarring may also occur in affected areas.

Cosentyx can reduce the number of nodules and abscesses you have and the pain that is often associated with the disease. If you have hidradenitis suppurativa, you will first be given other medicines. If you do not respond well enough to these medicines, you will be given Cosentyx.

Cosentyx is used in adults with hidradenitis suppurativa and can be used alone or with antibiotics.

Psoriatic arthritis

Cosentyx is a medicine used to treat a condition called "psoriatic arthritis". This is an inflammatory disease of the joints, often accompanied by psoriasis. If you have active psoriatic arthritis, you will first be given other medicines. If you do not respond well enough to these medicines, you will be given Cosentyx to reduce the signs and symptoms of active psoriatic arthritis, improve physical function and slow down the damage to the cartilage and bone of the joints involved in the disease.

Cosentyx is used in the treatment of adults with active psoriatic arthritis and can be used alone or with another medicine called methotrexate.

Using Cosentyx in psoriatic arthritis will benefit you by reducing the signs and symptoms of the disease, slowing down the damage to the cartilage and bone of the joints and improving your ability to do normal daily activities.

Axial spondyloarthritis, including ankylosing spondylitis and non-radiographic axial spondyloarthritis

Cosentyx is a medicine for the treatment of the condition of ankylosing spondylitis and non-radiographic axial spondyloarthritis. These are inflammatory diseases primarily affecting the spine, since they cause inflammation of the spinal joints. If you have ankylosing spondylitis or non-radiographic axial spondyloarthritis, you will first be given other medicines. If you do not respond well enough to these medicines, you will be given Cosentyx to reduce the signs and symptoms of the disease, reduce inflammation and improve your physical function.

Cosentyx is used to treat adults with active ankylosing spondylitis and active non-radiographic axial spondyloarthritis.

Using Cosentyx in ankylosing spondylitis and non-radiographic axial spondyloarthritis will benefit you by reducing the signs and symptoms of your disease and improving your physical function.

Juvenile idiopathic arthritis (JIA), including enthesitis-related arthritis (ERA) and juvenile psoriatic arthritis (JPsA)

Cosentyx is a medicine used in patients 6 years of age and older to treat conditions of the juvenile idiopathic arthritis (JIA) including enthesitis-related arthritis (ERA) and juvenile psoriatic arthritis (JPsA). These conditions are inflammatory diseases affecting the joints and the places where tendons join the bones.

Using Cosentyx in enthesitis-related arthritis (ERA) and juvenile psoriatic arthritis (JPsA) will benefit you (or your child) by reducing the symptoms and improving your (or your child's) physical function.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- **you are sensitive (allergic)** to secukinumab, or to any of the additional ingredients contained in the medicine (listed in section 6 "Further Information"). If you think you may be allergic, refer to the doctor for advice before using Cosentyx.
- **you have an active infection** that your doctor considers significant.

Special warnings regarding use of the medicine

Before treatment with Cosentyx, tell the doctor or nurse if any of the following conditions apply to you:

- If you currently have an infection.
- If you suffer from long-term or repeated infections.
- If you have tuberculosis.
- If you ever had an allergic reaction to latex.
- If you have an inflammatory disease affecting your gut called Crohn's disease.
- If you have an inflammation of your large intestine called ulcerative colitis.
- If you had a recent vaccination or if you will receive a vaccination during treatment with Cosentyx.
- If you are receiving any other treatment for psoriasis, such as another immunosuppressant or phototherapy with ultraviolet (UV) light.

Inflammatory bowel disease (Crohn's disease or ulcerative colitis)

Stop using Cosentyx and tell your doctor or seek medical help immediately if you notice abdominal cramps and pain, diarrhea, weight loss, blood in the stool or any other sign of a bowel problem.

Look out for infections and allergic reactions

Cosentyx can potentially cause serious side effects, including infections and allergic reactions. You must look out for signs of these conditions while you are taking Cosentyx.

Stop using Cosentyx and tell the doctor or seek medical help immediately if you notice any of the signs indicating a possible serious infection or an allergic reaction. The signs are listed under "Serious side effects" in section 4.

Children and adolescents

Cosentyx is not intended for children younger than 6 years of age with plaque psoriasis because the preparation has not been studied in this age group.

Cosentyx is not intended for children younger than 6 years of age with juvenile idiopathic arthritis (JIA), including enthesitis-related arthritis (ERA) and juvenile psoriatic arthritis (JPsA).

Cosentyx is not intended to treat other indications in children and adolescents (under 18 years of age) because it has not been studied in this age group.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist:

- if you have recently had or are going to have a vaccination. You should not receive certain types of vaccines (live vaccines) while using Cosentyx.

Pregnancy, breastfeeding and fertility

- It is preferable to avoid the use of Cosentyx during pregnancy. The effects of this medicine in pregnant women are not known. If you are a woman of childbearing potential, you are advised to avoid becoming pregnant by using adequate contraception while using Cosentyx and for at least 20 weeks after the last Cosentyx dose.
  Tell your doctor if you are pregnant, think you may be pregnant or are planning a pregnancy.
- Tell your doctor if you are breastfeeding or are planning to breastfeed. You and your doctor will decide if you should breastfeed or use Cosentyx. You should not do both. After using Cosentyx, do not breastfeed for at least 20 weeks after the last Cosentyx dose.

Driving and use of machines

Cosentyx is not expected to affect your ability to drive or use machines.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use Cosentyx according to the doctor's instructions. Check with the doctor, nurse or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation. The dosage and treatment regimen will be determined by the doctor only.

Cosentyx is given via injection under the skin (an injection called subcutaneous). You and your doctor should decide if you should inject Cosentyx yourself.

It is important not to try to inject yourself until you have been trained by your doctor, nurse or pharmacist. A caregiver may also give you your Cosentyx injection after proper training.

For detailed instructions on how to inject Cosentyx, see "Instructions for use of Cosentyx 150 mg solution for injection, in a pre-filled pen, Cosentyx SensoReady-pen", at the end of this leaflet.

Treatment duration

The doctor will decide how much Cosentyx you need and for how long.

Plaque psoriasis

Adults

- The recommended dose is 300 mg by subcutaneous injection
- Each 300 mg dose **is given as two subcutaneous injections of 150 mg**

After the first dose, you will receive further weekly injections at weeks 1, 2, 3 and 4, and then once a month. Based on your response, further adjustments of your dosage may be recommended by your doctor. At each timepoint you will receive a 300 mg dose given as two injections of 150 mg each.

Children aged 6 years and older

The recommended dose is based on body weight as follows:

- Weight below 25 kg: 75 mg by subcutaneous injection.
- Weight 25 kg or above and below 50 kg: 75 mg by subcutaneous injection.
- Weight 50 kg or above: 150 mg by subcutaneous injection. Your doctor may increase the dose to 300 mg.

Each 150 mg dose **is given as one injection of 150 mg.** Other dosage forms/strengths are available for administration of the 75 mg and 300 mg doses.

After the first dose, you will receive weekly injections at weeks 1, 2, 3 and 4, and then once a month.

Hidradenitis suppurativa

- The recommended dose is 300 mg by subcutaneous injection
- Each 300 mg dose is **given as two injections of 150 mg**

After the first dose you will receive further weekly injections at weeks 1, 2, 3 and 4 followed by monthly injections. Based on your response, further adjustments to your dose may be recommended by your doctor.

Psoriatic arthritis

For psoriatic arthritis patients who also have moderate to severe plaque psoriasis or patients who did not respond well to medicines called tumor necrosis factor (TNF) blockers:

- The recommended dose is 300 mg by subcutaneous injection
- Each 300 mg dose **is given as two subcutaneous injections of 150 mg**

After the first dose, you will receive further weekly injections at weeks 1, 2, 3 and 4, and then once a month. At each timepoint you will receive a 300 mg dose given as two injections of 150 mg each.

For other psoriatic arthritis patients

- The recommended dose is 150 mg by subcutaneous injection

After the first dose, you will receive further weekly injections at weeks 1, 2, 3 and 4, and then once a month.

Depending on your reaction, your doctor may increase the dose to 300 mg.

Ankylosing spondylitis

- The recommended dose is 150 mg by subcutaneous injection

After the first dose, you will receive further weekly injections at weeks 1, 2, 3 and 4, and then once a month.

Based on your response, your doctor may increase the dose to 300 mg. Each 300 mg dose is given as two injections of 150 mg.

Non-radiographic axial spondyloarthritis

- The recommended dose is 150 mg by subcutaneous injection

After the first dose, you will receive further weekly injections at weeks 1, 2, 3 and 4, and then once a month. Alternatively, after the first dose, your doctor may decide that a monthly injection is necessary.

Juvenile idiopathic arthritis (JIA) (enthesitis-related arthritis ERA and juvenile psoriatic arthritis JPsA)

The recommended dose is based on body weight as follows:

- Weight below 50 kg: 75 mg by subcutaneous injection.
- Weight 50 kg or above: 150 mg by subcutaneous injection.

Each 150 mg dose **is given as one injection of 150 mg.** Other dosage forms/strengths are available for administration of the 75 mg dose.

After the first dose, you will receive further weekly injections at weeks 1, 2, 3 and 4, and then once a month.

Cosentyx is a long-term treatment. The doctor will regularly monitor your condition to check that the treatment is having the desired effect.

Do not exceed the recommended dose.

If you took a higher Cosentyx dosage than required

If you took an overdose or if the dose was given sooner than according to your doctor's prescription, or if a child accidentally swallowed the medicine or injected it into himself, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to inject Cosentyx

If you forgot to inject a dose of Cosentyx at the designated time, inject the next dose as soon as you remember. Then talk to the doctor to discuss when you should inject the next dose.

Adhere to the treatment regimen as recommended by the doctor.

If you stop using Cosentyx

It is not dangerous to stop using Cosentyx. However, if you discontinue, the psoriasis, psoriatic arthritis or axial spondyloarthritis symptoms may come back.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Cosentyx may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Serious side effects

- Stop using Cosentyx and inform the doctor or seek medical help immediately if you suffer from any of the following side effects:

Signs of a **possibly serious infection** may include:

- fever, flu-like symptoms, night sweats.
- feeling tired or short of breath, cough which does not go away.
- warm, red and painful skin, or a painful skin rash with blisters.
- burning sensation when passing urine.

Signs of a **serious allergic reaction** may include:

- difficulty breathing or swallowing.
- low blood pressure, which can cause dizziness or light-headedness.
- swelling of the face, lips, tongue or throat.
- severe itching of the skin, with a red rash or raised bumps.

Your doctor will decide if and when you may restart the treatment.

Other side effects

Most of the side effects mentioned below are mild to moderate. If any of these side effects become severe, please refer to the doctor, pharmacist or nurse.

Very common side effects (effects that occur in more than 1 in 10 users):

- upper respiratory tract infections with symptoms, such as sore throat and stuffy nose (nasopharyngitis, rhinitis).

Common side effects (effects that occur in up to 1 in 10 users out of 100):

- cold sores (oral herpes)
- diarrhea
- runny nose (rhinorrhea)
- headache
- nausea
- fatigue

Uncommon side effects (effects that occur in 1-10 users out of 1,000):

- oral thrush (oral candidiasis)
- signs of low levels of white blood cells, such as fever, sore throat or mouth ulcers due to infections (neutropenia)
- infection of the external ear (otitis externa)
- discharge from the eye with itching, redness and swelling (conjunctivitis)
- itchy rash (urticaria)
- lower respiratory tract infections
- abdominal cramps and pain, diarrhea, weight loss or blood in the stool (signs of bowel problems)
- small, itchy blisters on the palms of hands, soles of feet and edges of the fingers and toes (dyshidrotic eczema)
- athlete's foot

Rare side effects (effects that occur in 1-10 users out of 10,000):

- severe allergic reaction with anaphylactic shock
- redness and peeling of skin over a large area of the body, which may be itchy or painful (exfoliative dermatitis)
- inflammation of small blood vessels, which can lead to a skin rash with small red or purple bumps (vasculitis)

Side effects of unknown frequency (effects whose frequency has not yet been determined):

- fungal infection of the skin and mucous membranes (including *Candida* [a type of fungus] of the esophagus)
- painful swelling and skin ulceration (pyoderma gangrenosum)

If a side effect occurs, if any of the side effects worsen or if you suffer from a side effect not listed in this leaflet, consult the doctor.

Reporting of side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package or on the label of the pre-filled pen. The expiry date refers to the last day of that month.
- Do not use if the liquid contains easily visible particles, if it is cloudy or is distinctly brown.

Storage conditions:

Store Cosentyx in the original box to protect it from light. Store it in the refrigerator between 2°C and 8°C. Do not freeze. Do not shake. If necessary, Cosentyx can be stored outside of the refrigerator for a single period of up to 4 days at room temperature, but not above 30°C.

Cosentyx is intended for single use only.

Do not throw away medicines via wastewater or household waste. Consult your pharmacist on how to dispose of medicines that are no longer in use. These measures will help to protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Water for injection, Trehalose dihydrate, L-histidine/histidine hydrochloride monohydrate, L-methionine and Polysorbate 80 low peroxide quality.

What the medicine looks like and the contents of the package:

Cosentyx solution for injection is a clear liquid. Its color can vary from colorless to slightly yellow.

Each package contains 1 or 2 SensoReady pre-filled pens (not all pack sizes may be marketed).

Registration Holder and Importer and its address: Novartis Israel Ltd., P.O.B 7126, Tel Aviv.

Revised in November 2023 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 154 20 34342

Instructions for use of Cosentyx 150 mg solution for injection, in a pre-filled pen, Cosentyx SensoReady-pen

Cosentyx SensoReady-pen 150 mg
Solution for injection in a pre-filled pen

Secukinumab
Patient Instructions for Use

Read all the way through these instructions before injecting.

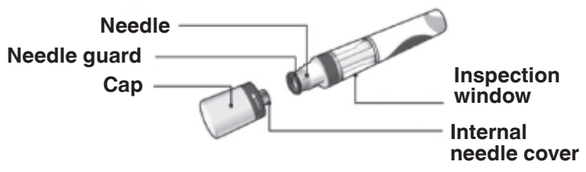
These instructions are to help you use the Cosentyx SensoReady-pen correctly.

It is important not to try to inject yourself or a person in your care until you have been trained by your doctor, nurse or pharmacist.

Your Cosentyx SensoReady-pen:

Store your pen in the box **in the refrigerator,** between 2°C and 8°C, **and out of the reach of children.**

- Do not **freeze** the pen.
- Do not **shake** the pen.
- Do not use the pen if it has been **dropped** after the cap has been removed.



Cosentyx SensoReady-pen shown with the cap removed.
Do not remove the cap until you are ready to inject.

For a more comfortable injection, take the pen out of the refrigerator **15-30 minutes before injection** to allow it to reach room temperature.

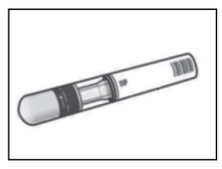
What you need for your injection:

Included in the carton:
A new Cosentyx SensoReady-pen (one pen is necessary for a 150 mg dose and two pens are necessary for a 300 mg dose).

Not included in the carton:
- Alcohol swab
- Cotton ball or gauze.
- Sharps disposal container.

Before the injection:

1. Important safety checks before you inject:



The liquid must be clear. Its color may vary from colorless to slightly yellow.

Do not use the solution if it contains easily visible particles, is cloudy or is brown.

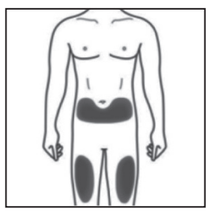
You may see a small air bubble, which is normal.

Do not use the pen **after the expiry date.**

Do not use the pen if **the safety seal** has been broken.

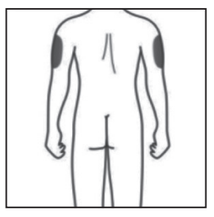
Refer to the pharmacist if the pen fails any of these checks.

2. a. Choose the injection site:



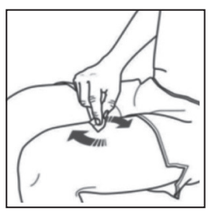
- The recommended site is the front of the thighs. You may also use the lower abdomen, but **not** the area 5 cm around the navel (belly button).
- Choose a different site each time you give yourself an injection.
- Do not inject into areas where the skin is tender, bruised, red, scaly or hard. Avoid areas with scars or stretch marks.

2. b. For caregivers and medical staff members only:



- If **a caregiver** or **medical staff member** is giving you the injection, they may also inject into the outer upper arm.

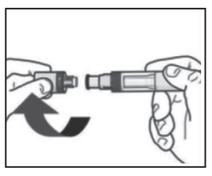
3. Cleaning the injection site:



- Wash your hands with soap and hot water.
- Using a circular motion, clean the injection site with the alcohol swab. Allow it to dry before injecting.
- Do not touch the cleaned area again before injecting.

The injection:

4. Removing the cap:



- Only remove the cap when you are ready to use the pen.
- Remove the cap by twisting it in the direction of the arrows.
- Once removed, throw away the cap.
- **Do not try to re-attach the cap.**
- Use the pen within 5 minutes of removing the cap.

5. Holding your pen

Hold the pen at 90° degrees to the cleaned injection site.

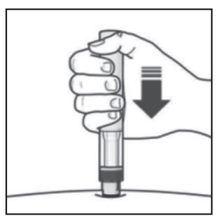
You must read this before injecting

During the injection, you will hear **2 loud clicks.**

The first click indicates the injection has started. Several seconds later, **a second click** will indicate that the injection is **almost** finished.

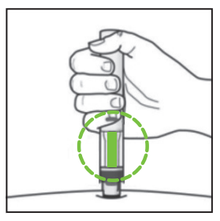
Continue firmly holding the pen against the skin until you see that **the green indicator** has filled the inspection window and has stopped moving.

6. Starting the injection:



- Press the pen firmly against the skin to start the injection.
- **The first click** indicates that the injection has started.
- **Keep holding** the pen firmly against the skin.
- **The green indicator** shows the progress of the injection.

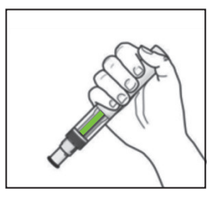
7. Completing the injection:



- Wait for **the second click**. It indicates that the injection is **almost** complete.
- Make sure that **the green indicator** has filled the window and has stopped moving.
- The pen can now be removed.

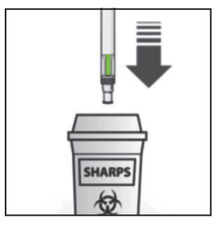
After the injection:

8. Make sure that the green indicator has filled the window:



- This means that the medicine has been injected. Refer to the doctor if the green indicator is not visible.
- There may be a small amount of blood at the injection site. You can press a cotton ball or gauze over the injection site and hold it for 10 seconds. Do not rub the injection site. You can cover the injection site with an adhesive bandage if needed.

9. Disposing of the Cosentyx SensoReady-pen



- Dispose of the used pen in a sharps disposal container (i.e., a puncture-resistant closable container or similar).
- Never reuse your pen.

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Cosentyx® 300 mg solution for injection

Solution for injection in a pre-filled pen (UnoReady-pen®) *for subcutaneous injection*

Active ingredient:
Each pre-filled Cosentyx pen (UnoReady-pen) contains 300 mg secukinumab in 2 ml of solution.

Inactive and allergenic ingredients in the preparation: see section 6 "Further Information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed to treat your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Cosentyx is intended for the treatment of the following inflammatory diseases:

- Plaque psoriasis:
  Cosentyx is intended for the treatment of moderate to severe plaque psoriasis in adults, adolescents and children aged 6 years and older who are candidates for systemic therapy.
- Hidradenitis suppurativa (HS):
  Cosentyx is intended to treat moderate to severe active hidradenitis suppurativa (acne inversa), in adults whose response to conventional systemic treatment is insufficient.
- Psoriatic arthritis:
  Treatment with Cosentyx or combination therapy of Cosentyx together with a medicine called methotrexate (MTX) is intended for the treatment of active psoriatic arthritis in adults when the response to previous treatment with a DMARD-type (disease-modifying anti-rheumatic drug) medicine was inadequate.
- Ankylosing spondylitis (radiographic axial spondyloarthritis):
  Cosentyx is intended for the treatment of active ankylosing spondilitis in adults when the response to previous conventional (routine) treatment was inadequate.

Therapeutic group: Interleukin (IL) Inhibitors.

The active ingredient in Cosentyx is secukinumab, a monoclonal antibody which belongs to a group of preparations called interleukin (IL) inhibitors. The medicine works by neutralizing the activity of a protein called IL-17A, which is present at increased levels in diseases such as psoriasis, psoriatic arthritis and axial spondyloarthritis.

Plaque psoriasis
Consentyx is a medicine used as a treatment of the skin for the condition of plaque psoriasis, which causes inflammation affecting the skin. Cosentyx reduces the inflammation and other symptoms of the disease. Cosentyx is used to treat adults, adolescents and children aged 6 years and older with moderate to severe plaque psoriasis.
Using Cosentyx in plaque psoriasis will benefit you by leading to improvements of skin clearance and reducing your symptoms such as scaling, itching and pain.

Hidradenitis suppurativa (HS)
Cosentyx is used to treat a condition called hidradenitis suppurativa, also sometimes called acne inversa or Verneuil's disease. This condition is a chronic and painful inflammatory skin disease, and its symptoms may include tender nodules (lumps) and abscesses (boils) that may leak pus. This condition commonly affects specific areas of the skin, such as: under the breasts, the armpits, inner thighs, groin and buttocks. Scarring may also occur in affected areas.
Cosentyx can reduce the number of nodules and abscesses you have and the pain that is often associated with the disease. If you have hidradenitis suppurativa, you will first be given other medicines. If you do not respond well enough to these medicines, you will be given Cosentyx.
Cosentyx is used in adults with hidradenitis suppurativa and can be used alone or with antibiotics.

Psoriatic arthritis
Cosentyx is a medicine used to treat a condition called "psoriatic arthritis". This is an inflammatory disease of the joints, often accompanied by psoriasis. If you have active psoriatic arthritis, you will first be given other medicines. If you do not respond well enough to these medicines, you will be given Cosentyx to reduce the signs and symptoms of active psoriatic arthritis, improve physical function and slow down the damage to the cartilage and bone of the joints involved in the disease.
Cosentyx is used in the treatment of adults with active psoriatic arthritis and can be used alone or with another medicine called methotrexate.
Using Cosentyx in psoriatic arthritis will benefit you by reducing the signs and symptoms of the disease, slowing down the damage to the cartilage and bone of the joints and improving your ability to do normal daily activities.

Ankylosing spondylitis (radiographic axial spondyloarthritis)
Cosentyx is a medicine for the treatment of the condition of ankylosing spondylitis. This is an inflammatory disease primarily affecting the spine, since it causes inflammation of the spinal joints. If you have ankylosing spondylitis, you will first be given other medicines. If you do not respond well enough to these medicines, you will be given Cosentyx to reduce the signs and symptoms of the disease, reduce inflammation and improve your physical function.
Cosentyx is used to treat adults with active ankylosing spondylitis.
Using Cosentyx in ankylosing spondylitis will benefit you by reducing the signs and symptoms of your disease and improving your physical function.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:
- you are sensitive (allergic) to secukinumab, or to any of the additional ingredients contained in the medicine (listed in section 6 "Further Information"). If you think you may be allergic, refer to the doctor for advice before using Cosentyx.
- you have an active infection that your doctor considers significant.

Special warnings regarding use of the medicine:
Before treatment with Cosentyx, tell the doctor or nurse if any of the following conditions apply to you:
- If you currently have an infection.
- If you suffer from long-term or repeated infections.
- If you have tuberculosis.
- If you have an inflammatory disease affecting your gut called Crohn's disease.
- If you have an inflammation of your large intestine called ulcerative colitis.
- If you had a recent vaccination or if you will receive a vaccination during treatment with Cosentyx.
- If you are receiving any other treatment for psoriasis, such as another immunosuppressant or phototherapy with ultraviolet (UV) light.

Inflammatory bowel disease (Crohn's disease or ulcerative colitis)
Stop using Cosentyx and tell your doctor or seek medical help immediately if you notice abdominal cramps and pain, diarrhea, weight loss, blood in the stool or any other sign of a bowel problem.

Watch out for infections and allergic reactions
Cosentyx can potentially cause serious side effects, including infections and allergic reactions. You must look out for signs of these conditions while you are taking Cosentyx.
Stop using Cosentyx and tell the doctor or seek medical help immediately if you notice any of the signs indicating a possible serious infection or an allergic reaction. The signs are listed under "Serious side effects" in section 4.

Children and adolescents
Cosentyx is not intended for children younger than 6 years of age with plaque psoriasis because the preparation has not been studied in this age group.
Cosentyx is not intended for children and adolescents (under 18 years of age) for treatment in other indications because the preparation has not been studied in this age group.

Drug interactions
If you are taking or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist:
- if you have recently had or are going to have a vaccination. You should not receive certain types of vaccines (live vaccines) while using Cosentyx.

Pregnancy, breastfeeding and fertility
- It is preferable to avoid the use of Cosentyx during pregnancy. The effects of this medicine in pregnant women are not known. If you are a woman of childbearing potential, you are advised to avoid becoming pregnant by using adequate contraception while using Cosentyx and for at least 20 weeks after the last Cosentyx dose.
  Tell your doctor if you are pregnant, think you may be pregnant or are planning a pregnancy.
- Tell your doctor if you are breastfeeding or are planning to breastfeed. You and your doctor will decide if you should breastfeed or use Cosentyx. You should not do both. After using Cosentyx do not breastfeed for at least 20 weeks after the last Cosentyx dose.

Driving and use of machines
Cosentyx is not expected to affect your ability to drive or use machines.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use Cosentyx according to the doctor's instructions. Check with the doctor, nurse or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.
The dosage and treatment regimen will be determined by the doctor only.
Cosentyx is given via injection under the skin (an injection called subcutaneous). You and your doctor should decide if you should inject Cosentyx yourself.
It is important not to try to inject yourself until you have been trained by your doctor, nurse or pharmacist. A caregiver may also give you your Cosentyx injection after proper training.
For detailed instructions on how to inject Cosentyx, see "Instructions for use of Cosentyx 300 mg solution for injection, in a pre-filled pen, Cosentyx UnoReady-pen" at the end of this leaflet.

Treatment duration
The doctor will decide how much Cosentyx you need and for how long.

Plaque psoriasis
Adults
- The recommended dose is 300 mg by subcutaneous injection
- Each 300 mg dose **is given as one subcutaneous injection of 300 mg**

After the first dose, you will receive further weekly injections at weeks 1, 2, 3 and 4, and then once a month. Based on your response, further adjustments to your dosage may be recommended by your doctor. At each timepoint you will receive a 300 mg dose given as one injection of 300 mg.

Children aged 6 years and older
The recommended dose is based on body weight as follows:
- Weight below 25 kg: 75 mg by subcutaneous injection.
- Weight 25 kg or above and below 50 kg: 75 mg by subcutaneous injection.
- Weight 50 kg or above: 150 mg by subcutaneous injection.
  Your doctor may increase the dose to 300 mg.

Each 300 mg dose **is given as one injection of 300 mg.**
Other dosage forms/strengths are available for administration of the 75 mg and 150 mg doses.
After the first dose you will receive weekly injections at weeks 1, 2, 3 and 4 followed by monthly injections.

Hidradenitis suppurativa
- The recommended dose is 300 mg by subcutaneous injection
- Each 300 mg dose **is given as one injection of 300 mg**.

After the first dose you will receive further weekly injections at weeks 1, 2, 3 and 4 followed by monthly injections. Based on your response, further adjustments to your dose may be recommended by your doctor.

Psoriatic arthritis
For psoriatic arthritis patients who also have moderate to severe plaque psoriasis or patients who did not respond well to medicines called tumor necrosis factor (TNF) blockers:
- The recommended dose is 300 mg by subcutaneous injection
- Each 300 mg dose **is given as one subcutaneous injection of 300 mg**

After the first dose, you will receive further weekly injections at weeks 1, 2, 3 and 4, and then once a month. At each timepoint you will receive a 300 mg dose **given as one injection of 300 mg.**

For other psoriatic arthritis patients
- The recommended dose is 150 mg by subcutaneous injection. Other dosage forms/strengths are available for the 150 mg dose.

After the first dose, you will receive further weekly injections at weeks 1, 2, 3 and 4, and then once a month.
Depending on your reaction, your doctor may increase the dose to 300 mg.

Ankylosing spondylitis
- The recommended dose is 150 mg by subcutaneous injection. Other dosage forms/strengths are available for the 150 mg dose.

After the first dose, you will receive further weekly injections at weeks 1, 2, 3 and 4, and then once a month.
Based on your response, your doctor may increase the dose to 300 mg. Each 300 mg dose **is given as one injection of 300 mg.**
Cosentyx is for long-term treatment. The doctor will regularly monitor your condition to check that the treatment is having the desired effect.

Do not exceed the recommended dose.

If you took a higher Cosentyx dosage than required
If you took an overdose or if the dose was given sooner than according to your doctor's prescription, or if a child accidentally swallowed the medicine or injected it into himself, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to inject Cosentyx
If you forgot to inject a dose of Cosentyx at the designated time, inject the next dose as soon as you remember. Then talk to the doctor to discuss when you should inject the next dose. Adhere to the treatment regimen recommended by the doctor.

If you stop using Cosentyx
It is not dangerous to stop using Cosentyx. However, if you discontinue, the psoriasis, psoriatic arthritis or ankylosing spondylitis symptoms from which you suffered may come back.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Cosentyx may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Serious side effects
Stop using Cosentyx and inform the doctor or seek medical help immediately if you suffer from any of the following side effects:
Signs **of a possibly serious infection** may include:
- fever, flu-like symptoms, night sweats.
- feeling tired or short of breath, cough which does not go away.
- warm, red and painful skin, or a painful skin rash with blisters.
- burning sensation when passing urine.

Signs of **a serious allergic reaction** may include:
- difficulty breathing or swallowing.
- low blood pressure, which can cause dizziness or light-headedness.
- swelling of the face, lips, tongue or throat.
- severe itching of the skin, with a red rash or raised bumps.

Your doctor will decide if and when you may restart the treatment.

Other side effects
Most of the side effects mentioned below are mild to moderate. If any of these side effects become severe, please refer to the doctor, pharmacist or nurse.

Very common side effects (effects that occur in more than 1 in 10 users):
- upper respiratory tract infections with symptoms such as sore throat and stuffy nose (nasopharyngitis, rhinitis).

Common side effects (effects that occur in up to 1 in 10 users out of 100):
- cold sores (oral herpes)
- diarrhea
- runny nose (rhinorrhea)
- headache
- nausea
- fatigue

Uncommon side effects (effects that occur in 1-10 users out of 1,000):
- oral thrush (oral candidiasis)
- signs of low levels of white blood cells, such as fever, sore throat or mouth ulcers due to infections (neutropenia)
- infection of the external ear (otitis externa)
- discharge from the eye with itching, redness and swelling (conjunctivitis).
- itchy rash (urticaria)
- lower respiratory tract infections
- abdominal cramps and pain, diarrhea, weight loss or blood in the stool (signs of bowel problems)
- small, itchy blisters on the palms of hands, soles of feet and edges of the fingers and toes (dyshidrotic eczema)
- athlete's foot

Rare side effects (effects that occur in 1-10 users out of 10,000):
- severe allergic reaction with anaphylactic shock
- redness and peeling of skin over a large area of the body, which may be itchy or painful (exfoliative dermatitis)
- inflammation of small blood vessels, which can lead to a skin rash with small red or purple bumps (vasculitis)

Side effects of unknown frequency (effects whose frequency has not yet been determined):
- fungal infection of the skin and mucous membranes (including Candida [a type of fungus] of the esophagus)
- painful swelling and skin ulceration (pyoderma gangrenosum)

If a side effect occurs, if any of the side effects worsen or if you suffer from a side effect not listed in this leaflet, consult the doctor.

Reporting of side effects
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package or on the label of the pre-filled pen. The expiry date refers to the last day of that month.
- Do not use if the liquid contains easily visible particles, if it is cloudy or is distinctly brown.

Storage conditions:
Store Cosentyx in the original box to protect it from light. Store it in the refrigerator between 2°C and 8°C. Do not freeze. Do not shake. If necessary, Cosentyx can be stored outside of the refrigerator for a single period of up to 4 days at room temperature, but not above 30°C.
Cosentyx is intended for single use only.
Do not throw away medicines via wastewater or household waste. Consult your pharmacist on how to dispose of medicines that are no longer in use. These measures will help to protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
Water for injection, Trehalose dihydrate, L-histidine/L-histidine hydrochloride monohydrate, L-methionine and Polysorbate 80 low peroxide quality.

What the medicine looks like and the contents of the package:
Cosentyx solution for injection is a clear liquid. Its color can vary from colorless to slightly yellow.
Each package contains 1 or 3 UnoReady pre-filled pens (not all pack sizes may be marketed).

Registration Holder and Importer and its address:
Novartis Israel Ltd., P.O.B 7126, Tel Aviv.

Revised in November 2023 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 154 20 34342

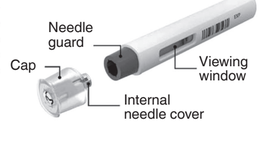
Instructions for use of Cosentyx 300 mg solution for injection, in a pre-filled pen, Cosentyx UnoReady-pen.

Cosentyx UnoReady-pen 300 mg
Solution for injection in a pre-filled pen
secukinumab
Patient Instructions for Use

Read all the way through these instructions before injecting.
These instructions are to help you use the Cosentyx UnoReady-pen correctly.
It is important not to try to inject yourself or the person in your care until you have been trained by your doctor, nurse or pharmacist.

Your Cosentyx UnoReady-pen:
Store your pen in the box **in the refrigerator**, between 2°C and 8°C **and out of the reach of children**.
- Do not freeze the pen.
- Do not shake the pen.
- Do not use the pen if it **has been dropped** after the cap has been removed.

Cosentyx UnoReady-pen shown with the cap removed. Do not remove the cap until you are ready to inject.



The needle is covered by the needle guard and is not visible. Do not touch or press the needle guard as you may be injured by the needle.

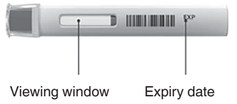
For a more comfortable injection, take the pen out of the refrigerator **30-45 minutes before injection** to allow it to reach room temperature.

What you need for your injection:

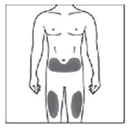
Included in the carton:	Not included in the carton:
A new Cosentyx UnoReady-pen	Alcohol swab Cotton ball or gauze Sharps disposal container

Before the injection:

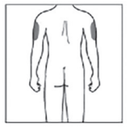
1. Important safety checks before you inject:
The liquid in the viewing window must be clear. Its color may vary from colorless to slightly yellow.
Do not use the solution if it contains easily visible particles, is cloudy or is brown.
You may see a small air bubble, which is normal.
Do not use the pen **after the expiry date.**
Do not use the pen if the **safety seal** is broken.
Refer to the pharmacist if the pen fails any of these checks.



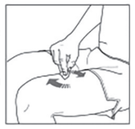
2. a. Choose the injection site:
- The recommended site is the front of the thighs. You may also use the lower abdomen, but not the area 5 cm around the navel (belly button).
- Choose a different site each time you give yourself an injection.
- Do not inject into areas where the skin is tender, bruised, red, scaly or hard. Avoid areas with scars or stretch marks.



2. b. For caregivers and medical staff members only:
- If a caregiver or medical staff member is giving you the injection, they may also inject into the outer upper arm.

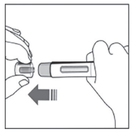


3. Cleaning the injection site:
- Wash your hands with soap and hot water.
- Using a circular motion, clean the injection site with the alcohol swab. Allow it to dry before injecting.
- Do not touch the cleaned area again before injecting.

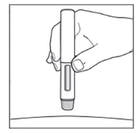


The injection:

4. Removing the cap:
- Only remove the cap when you are ready to use the pen.
- Remove the cap by twisting it in the direction of the arrows.
- Once removed, throw away the cap.
- **Do not try to re-attach the cap.**
- Use the pen within 5 minutes of removing the cap.



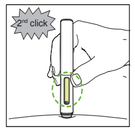
5. Holding your pen
Hold the pen at 90° degrees to the cleaned injection site.



You must read this before injecting
During the injection, you will hear **2 loud clicks**.
The first click indicates the injection has started. Several seconds later, **a second click** will indicate that the injection is **almost** finished.
Continue firmly holding the pen against the skin until you see that **the green indicator** has filled the viewing window and has stopped moving.

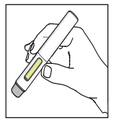
6. Starting the injection:
- Press the pen firmly against the skin to start the injection.
- **The first click** indicates that the injection has started.
- **Keep holding** the pen firmly against the skin.
- **The green indicator** shows the progress of the injection.

7. Completing the injection:
- Wait for **the second click**. It indicates that the injection is **almost** complete.
- Make sure that **the green indicator** has filled the window and has stopped moving.
- The pen can now be removed.



After the injection:

8. Make sure that the green indicator has filled the window:
- This means that the medicine has been injected. Refer to the doctor if the green indicator is not visible.
- There may be a small amount of blood at the injection site. You can press a cotton ball or gauze over the injection site and hold it for 10 seconds. Do not rub the injection site. You can cover the injection site with an adhesive bandage if needed.



9. Disposing of the Cosentyx UnoReady-pen
- Dispose of the used pen in a sharps disposal container (i.e., a puncture-resistant closable container or similar).
- Never reuse your pen.