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/ml secukinumab.
Inactive and allergenic ingredients: 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 who are candidates for systemic therapy.
- 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 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 infection signs manifesting by increased levels of C-reactive protein (CRP) and 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 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.

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 enthesitisrelated 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 in Cosentyx (listed in section 6). 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 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.

<u>Plaque psoriasis</u>

- 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.

<u>Psoriatic arthritis</u>

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.

<u>For other psoriatic arthritis patients</u>

- 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.

<u>Ankylosing spondylitis</u>

- 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.

<u>Non-radiographic axial spondyloarthritis</u>

- 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.

<u>Juvenile idiopathic arthritis (JIA) (enthesitis-related arthritis ERA and juvenile psoriatic arthritis JPsA)</u>

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 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 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 <u>each time</u> 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 this medicine 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

· <u>Stop using Cosentyx and inform the doctor or seek medical help immediately</u> 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)
· athlete's foot
· 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)

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]

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 January 2023 according to MOH guidelines.

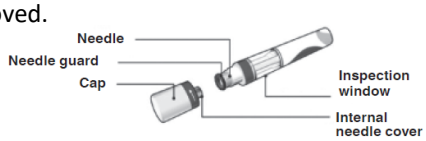
Registration number of the medicine in the National Drug Registry of the Ministry of Health: 154 20 34342

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 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.

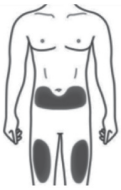
What you need for your injection:

Included in the carton:	Not included in the carton:
A new Cosentyx SensoReady-pen (two pens are necessary for a 300 mg dose)	• Alcohol swab • Cotton ball or gauze. • Sharps disposal container.

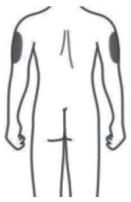
Before the injection:

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.

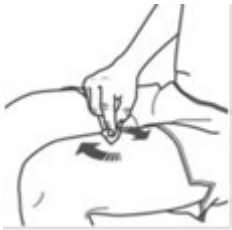


2. b. For caregivers and medical staff members only:
- If a caregiver or medical staff member is giving you the injection, they may also inject into the outer upper arm.



3. Cleaning the injection site:

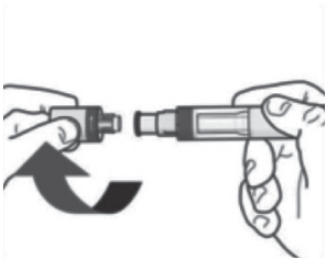
- Wash your hands with soap and hot water.
- Using a circular motion, clean the injection site with the alcohol swab. Allow it to dry before injecting.
- Do not touch the cleaned area again before injecting.



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

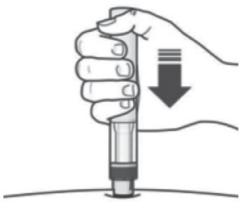
During the injection, you will hear **2 loud clicks**.

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.