

**Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986**

The dispensing of this medicine requires a doctor's prescription

# **Taltz 80 mg**

## **Solution for injection in a pre-filled pen**

### **The active ingredient and its quantity in dosage units:**

Each 1 mL contains 80 mg of ixekizumab.

Each pre-filled pen contains 80 mg of ixekizumab in 1 mL solution.

**Inactive ingredients and allergens in the preparation:** See chapter 2 section "Important information about some of the ingredients of this medicine" and chapter 6 "Additional Information".

**Read the entire leaflet carefully before using this medicine.** This leaflet contains concise information about this medicine. If you have any further questions, ask your doctor or pharmacist. This medicine has been prescribed for the treatment of your illness. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

This medicine is intended for adults over 18 years of age.

## **1. WHAT IS THIS MEDICINE INTENDED FOR?**

Taltz is intended for the treatment of the inflammatory diseases described below:

### Plaque psoriasis

Taltz is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

### Psoriatic arthritis

Taltz, alone or in combination with methotrexate, is indicated for the treatment of active psoriatic arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drug (DMARD) therapies.

### Ankylosing spondylitis (radiographic axial spondyloarthritis)

Taltz is indicated for the treatment of adult patients with active ankylosing spondylitis who have responded inadequately to conventional therapy.

### Non-radiographic axial spondyloarthritis

Taltz is indicated for the treatment of adult patients with active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and magnetic resonance imaging (MRI) who have responded inadequately to nonsteroidal anti-inflammatory drugs (NSAIDs).

**Therapeutic group:** Immunosuppressants, interleukin inhibitors.

Ixekizumab belongs to a group of medicines called interleukin (IL) inhibitors. This medicine works by blocking the activity of a protein called IL-17A, which promotes psoriasis and inflammatory disease of the joints and the spine.

Using Taltz will benefit you by improvements of skin clearance and reducing your symptoms such as scaling, itching and pain.

Using Taltz will benefit you by reducing the signs and symptoms of the disease, improving physical function (ability to do normal daily activities), and slowing down the damage to the joints.

## **2. BEFORE USING THIS MEDICINE**

### **Do not use this medicine if:**

- you are allergic (hypersensitive) to ixekizumab or any of the other ingredients of this medicine (listed in chapter 6). If you think you may be allergic, ask your doctor for advice before using Taltz.
- you have an infection which your doctor thinks is important (for example, active tuberculosis).

### **Special warnings regarding the use of this medicine**

#### **Before using Taltz, tell your doctor if you:**

- currently have an infection or if you have long-term or repeated infections.
- have an inflammatory disease affecting the gut named Crohn's disease.
- have an inflammation of the large intestine named ulcerative colitis.
- are receiving any other treatment for psoriasis (such as immunosuppressant or phototherapy with ultraviolet light) or for psoriatic arthritis.

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

Stop using Taltz and tell your doctor or seek medical help immediately if you notice abdominal cramps and pain, diarrhea, weight loss or blood in the stool (any signs of bowel problems).

If you are not sure if any of the above applies to you, talk to your doctor or nurse before using Taltz.

#### **Look out for infections and allergic reactions**

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

Stop using Taltz and tell your doctor or seek medical help immediately if you notice any signs of a serious infection or an allergic reaction. Such signs are listed under "Serious side effects" in chapter 4.

#### **Children and Adolescents**

Taltz is not intended for children and adolescents under the age of 18.

#### **Drug interactions**

**Tell your doctor, pharmacist or nurse if you are taking or have recently taken any other medicine, including nonprescription medicines and nutritional supplements.**

Tell your doctor, pharmacist or nurse:

- if you are using, have recently used or might use any other medicines.
- if you have recently had or are due to have a vaccination. You should not be given certain types of vaccines while using Taltz.

#### **Pregnancy and breastfeeding**

If you are pregnant, think you may be pregnant, or are planning to have a baby, ask your doctor for advice before using this medicine. It is preferable to avoid the use of Taltz 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 and must use effective contraception while using Taltz and for at least 10 weeks after the last Taltz dose.

If you are breastfeeding or are planning to breastfeed, talk to your doctor before using this medicine. You and your doctor should decide if you can breastfeed or use Taltz. You should not do both.

#### **Driving and using machines**

Taltz is unlikely to influence your ability to drive and use machines.

### **Important information about some of the ingredients of this medicine**

#### **Taltz contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per 80 mg dose, i.e., essentially “sodium-free”.

#### **Taltz contains polysorbate**

This medicine contains 0.30 mg of polysorbate 80 in each 80 mg pre-filled pen, which is equivalent to 0.30 mg/mL. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

### **3. HOW TO USE THIS MEDICINE?**

Always use this medicine exactly as your doctor has told you. Check with your doctor, nurse or pharmacist if you are not sure about the dosage and manner of treatment with this medicine.

The dosage and manner of treatment will be determined only by your doctor.

Taltz is given by injection under your skin (subcutaneous injection). You and your doctor or nurse should decide if you should inject Taltz yourself.

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

Use a reminder method such as notes in a calendar or diary to help you remember your next dose so that you avoid missing or repeating doses.

Taltz is for long-term treatment. Your doctor or nurse will regularly monitor your condition to check that the treatment is having the desired effect.

Each pen contains one dose of Taltz (80 mg). Each pen delivers only one dose. The pen must not be shaken.

Read the “Instructions for Use” for the pen carefully before using Taltz.

#### **The acceptable dosage of Taltz and for how long it is given**

Your doctor will explain to you how much Taltz you need and for how long.

#### Plaque psoriasis

- The first dose is 160 mg (2 pens with 80 mg each) by subcutaneous injection. This may be given by your doctor or nurse.
- After the first dose, you will use an 80 mg dose (1 pen) at weeks 2, 4, 6, 8, 10 and 12. From week 12, you will use an 80 mg dose (1 pen) every 4 weeks.

#### Psoriatic arthritis

For psoriatic arthritis patients who also have moderate to severe plaque psoriasis:

- The first dose is 160 mg (2 pens with 80 mg each) by subcutaneous injection. This may be given by your doctor or nurse.
- After the first dose, you will use an 80 mg dose (1 pen) at weeks 2, 4, 6, 8, 10, and 12. From week 12, you will use an 80 mg dose (1 pen) every 4 weeks.

#### For other psoriatic arthritis patients

- The first dose is 160 mg (2 pens with 80 mg each) by subcutaneous injection. This may be given by your doctor or nurse.
- After the first dose you will use an 80 mg dose (1 pen) every 4 weeks

### Axial spondyloarthritis

The recommended dose is 160 mg (2 pens with 80 mg each) by subcutaneous injection at week 0, followed by 80 mg (1 pen) every 4 weeks.

### **Do not exceed the recommended dose.**

### **If you have accidentally taken a higher dose**

If you have received more Taltz than you should or the dose has been given sooner than prescribed, inform your doctor.

If you have taken an overdose, or if a child has accidentally taken some medicine, contact a doctor or go immediately to a hospital Emergency Room and bring the medicine package with you.

### **If you forgot to use this medicine**

If you have forgotten to inject a dose of Taltz, talk to your doctor.

Persist with the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not discontinue treatment with this medicine without consulting the doctor.

### **If you stop using this medicine**

Do not stop using Taltz without speaking to your doctor first. If you stop treatment, symptoms of psoriasis or psoriatic arthritis may come back.

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

**If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.**

## **4. SIDE EFFECTS**

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

### **Serious side effects**

Stop using Taltz and tell your doctor or seek medical help immediately if you get any of the following side effects. Your doctor will decide if and when you may restart the treatment:

**Possible serious infection** (uncommon, may affect up to 1 in 100 people) - the signs may include:

- fever, flu-like symptoms, night sweats
- feeling tired or short of breath, cough which will not go away
- warm, red and painful skin, or a painful skin rash with blisters

**Serious allergic reaction** (rare, may affect up to 1 in 1,000 people) - the signs 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

### **Other side effects that have been reported:**

**Very common side effects** (may affect more than 1 in 10 people):

- upper respiratory tract infections with symptoms such as sore throat and stuffy nose
- injection site reactions (e.g. red skin, pain)

**Common side effects** (may affect up to 1 in 10 people):

- nausea
- fungal infections such as athlete's foot
- pain in the back of the throat
- cold sores of mouth, skin and mucous membranes (herpes simplex, mucocutaneous)

**Uncommon side effects** (may affect up to 1 in 100 people):

- oral thrush (oral candidiasis)
- influenza
- runny nose
- bacterial skin infection
- hives
- discharge from the eye with itching, redness and swelling (conjunctivitis)
- signs of low levels of white blood cells, such as fever, sore throat or mouth ulcers due to infections (neutropenia)
- low blood platelet count (thrombocytopenia)
- eczema
- painful, itchy and fluid-filled blisters (dyshidrotic eczema)
- rash
- rapid swelling of the tissues of the neck, face, mouth or throat (angioedema)
- abdominal cramps and pain, diarrhea, weight loss or blood in the stool (signs of bowel problems)

**Rare side effects** (may affect up to 1 in 1,000 people):

- fungal infection of the esophagus (esophageal candidiasis)
- redness and peeling of the skin (exfoliative dermatitis)

**If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.**

**Reporting side effects**

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting side effects due to drug treatment" that can be found on the Home Page of the Ministry of Health's website ([www.health.gov.il](http://www.health.gov.il)), which refers to an online form for reporting side effects, or by entering the following link:

<https://sideeffects.health.gov.il>

**5. HOW TO STORE THIS MEDICINE?**

Avoid poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place out of the sight and reach of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use this medicine after the expiry date (exp. date) which is stated on the pen label and on the outer carton. The expiry date refers to the last day of that month.

**Storage conditions:**

Store in a refrigerator (2°C – 8°C). Do not freeze. Do not push to the back panel of the fridge. Do not shake.

The patient may store the product unrefrigerated for up to 5 days at a temperature of up to 30°C.

Afterwards, the product must be discarded even if it hasn't been used.

Store in the original packaging in order to protect from light.

Do not use this medicine if you notice that the pen is damaged, or the medicine is cloudy, distinctly brown, or has particles in it.

This medicine is for single use only.

Do not throw away the medicine via wastewater or household waste. Ask your doctor or pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. ADDITIONAL INFORMATION**

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

sucrose; polysorbate 80; water for injection.

In addition, sodium hydroxide may have been added for pH adjustment (see section 2 “Taltz contains sodium” and “Taltz contains polysorbate”).

**What the medicine looks like and contents of the pack**

Taltz is a solution in a clear glass syringe. Its color may vary from colorless to slightly yellow to slightly brown.

The syringe is encased in a disposable, single-dose pen.

The package contains 1, 2, or 3 pre-filled pens.

Not all pack sizes may be marketed.

**Registration holder’s name and address:**

Eli Lilly Israel Ltd., 4 HaSheizaf St., P.O.Box 4246, Ra’anana 4366411

**Manufacturer’s name and address:**

Eli Lilly and Company, Lilly Corporate Center, Indianapolis, Indiana (IN) 46285, USA.

Revised in November 2025.

**Registration number of the medicine in the National Drug Registry of the Ministry of Health: 157-73-34927-00.**

## Instructions for use

### Taltz 80 mg solution for injection in pre-filled pen

Ixekizumab



Before using your pre-filled pen:

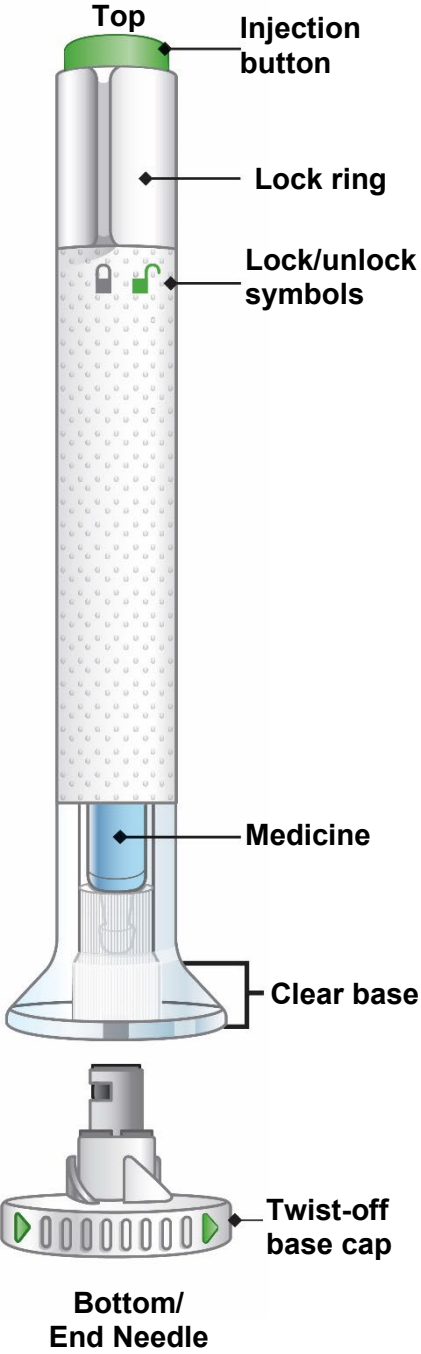
#### Important points to know

- Before you use the Taltz pre-filled pen, read and carefully follow all the step-by-step instructions. Keep the Instructions for Use and refer to them as needed.
- The pre-filled pen contains 1 dose of Taltz. The pre-filled pen is for ONE-TIME USE ONLY.
- The pre-filled pen must not be shaken.
- The pre-filled pen contains glass parts. Handle it carefully. If you drop it on a hard surface, do not use it. Use a new pre-filled pen for your injection.
- Your doctor, pharmacist or nurse may help you decide where on your body to inject your dose.
- Read the Taltz Patient Leaflet inside this box to learn more about your medicine.

#### INSTRUCTIONS FOR USE

**Before you use the Taltz pre-filled pen, read and carefully follow all the step-by-step instructions.**

Guide to the parts



## 1 GET READY

**1a Take the pre-filled pen from the refrigerator.** Leave the base cap on until you are ready to inject. **Wait 30 minutes** to let the pre-filled pen warm to room temperature before you use it.

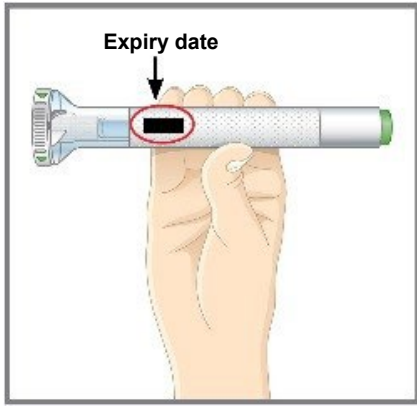
**DO NOT** use any heat sources to warm the medicine, for example: a microwave, hot water, or direct sunlight.

**1b Gather the supplies for your injection:**

- 1 alcohol wipe
- 1 cotton ball or piece of gauze
- 1 sharps container for disposal of pre-filled pen



1c



**Inspect the pre-filled pen.** Check the label. Make sure the name Taltz appears on the label.

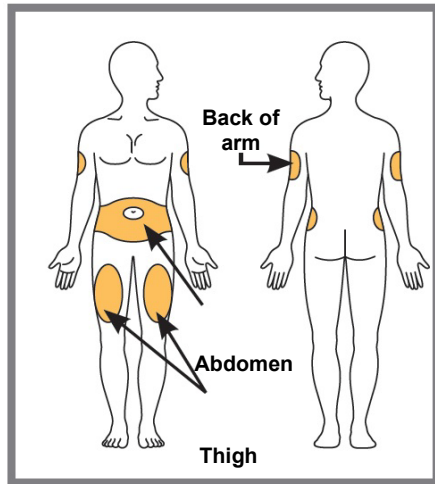
The medicine inside should be clear. Its color may vary from colorless to slightly yellow to slightly brown.

If you see any of the following, **DO NOT USE** the pre-filled pen, and dispose of it as directed:

- It is past the expiry date.
- It looks damaged.
- The medicine is cloudy, is distinctly brown, or has small particles.

1d **Wash your hands before you inject your medicine.**

1e



**Choose your injection site.**

You may inject in your abdomen (stomach area), in your thigh, or in the back of your arm. To inject in your arm, you will need someone to help you.

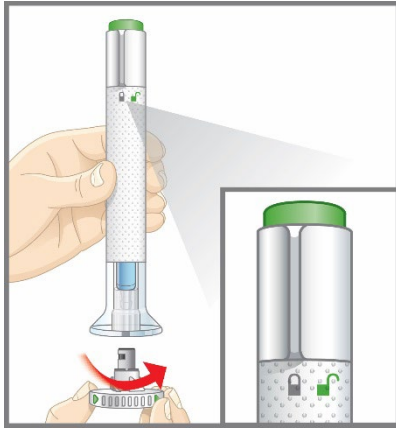
**DO NOT** inject into areas where the skin is tender, bruised, red, or hard or where you have scars or stretch marks. **DO NOT** inject within 2.5 centimetres of the navel (belly button).

**Alternate your injection sites. DO NOT** inject in the exact same spot every time. For example, if your last injection was in your left thigh, your next injection should be in your right thigh, your abdomen, or the back of either arm.

1f Prepare your skin. Clean your skin with an alcohol wipe. Let the injection site dry naturally before you inject your medicine.

## 2 INJECT

2a



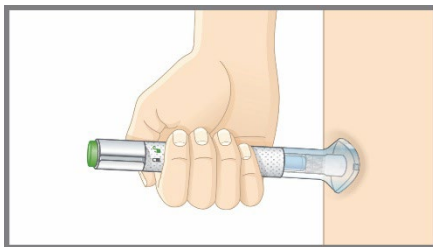
**Make sure the lock ring is in the lock position.**

Leave the base cap on until you are ready to inject. **DO NOT** touch the needle.

**Twist off the base cap.**

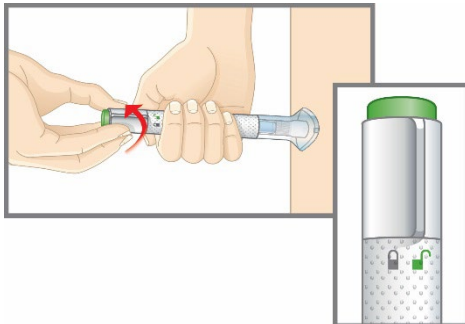
Throw the base cap in the bin. You will not need to put the base cap back on - doing so could damage the needle or cause you to injure yourself by accident.

2b



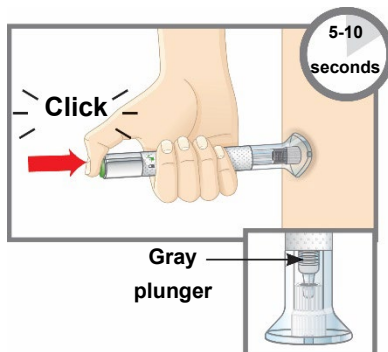
**Place the clear base flat and firmly against your skin.**

2c



**Keep the base on your skin, and then turn the lock ring to the unlock position.** You are now ready to inject.

2d



**Press the green injection button.** There will be a loud click.

**Keep holding the clear base firmly against your skin.** You will hear a second loud click in about 5 to 10 seconds after the first one. **The second loud click tells you that your injection is complete.**

You will also see the gray plunger at the top of the clear base.

Remove the pre-filled pen from your skin.

Press a cotton ball or gauze over the injection site. **DO NOT** rub the injection site, as this may cause bruising. You may have slight bleeding. This is normal.

### 3 FINISH

3a



**Dispose of the pre-filled pen.**

**DO NOT** put the base cap back on. Dispose of the pre-filled pen in a sharps container or as directed by your doctor, pharmacist or nurse.

#### **When you dispose of the pre-filled pen and the sharps container:**

- Dispose of the pen in a sharps container or as directed by your doctor, pharmacist or nurse.
- Do not recycle the filled sharps container.
- Ask your doctor, pharmacist or nurse about how to dispose of medicines you no longer use.

#### **Safety tips**

- If you have questions or need help with your pre-filled pen, call your doctor, pharmacist or nurse.
- If you have vision problems, **DO NOT** use the pre-filled pen without help from a person trained to use it.
- Keep the pre-filled pen out of the reach and sight of children.
- If you do not have a sharps container, ask your doctor, pharmacist or nurse where you can get one.

#### **Commonly asked questions**

**Q. What if I see air bubbles in the pre-filled pen?**

**A.** It is normal to have air bubbles in the pre-filled pen. Taltz is injected under the skin (subcutaneous injection). Air bubbles are not a problem in this type of injection. They will not harm you or affect your dose.

- Q. What if there is a drop of liquid on the tip of the needle when I remove the base cap?**
- A.** It is okay to see a drop of liquid on the tip of the needle. This will not harm you or affect your dose.
- Q. What if I unlocked the pre-filled pen and pressed the green injection button before I twisted off the base cap?**
- A.** Do not remove the base cap. Contact your doctor, pharmacist or nurse.
- Q. Do I need to hold the injection button down until the injection is complete?**
- A.** This is not necessary, but it may help you keep the pre-filled pen steady and firm against your skin.
- Q. What if the needle did not retract after my injection?**
- A.** Do not touch the needle or replace the base cap. Dispose of the pre-filled pen in a closable, puncture-resistant sharps container. Contact your doctor, pharmacist or nurse.
- Q. What if I heard more than 2 clicks during my injection—2 loud clicks and a soft one. Did I get my complete injection?**
- A.** Some patients may hear a soft click right before the second loud click. That is normal. Do not remove the pre-filled pen from your skin until you hear the second loud click.
- Q. How can I tell if my injection is complete?**
- A.** After you press the green injection button, you will hear 2 loud clicks. The second click tells you that your injection is complete. You will also see the gray plunger at the top of the clear base.
- Q. What if the pre-filled pen is left at room temperature for longer than 30 minutes?**
- A.** If needed, the pre-filled pen may be left out of the fridge at temperature not above 30°C for up to 5 days if protected from direct sunlight. Taltz should be discarded if not used within the 5 day period at room temperature.

**Read the full Instructions for use and the Patient Leaflet inside this box to learn more about your medicine.**