

TALTZ 80 MG SOLUTION FOR INJECTION IN PRE-FILED PEN

Ixekizumab 80 mg

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What Taltz is used for

Plaque psoriasis

Taltz is used to treat a skin condition called “plaque psoriasis” in adults and in children from the age of 6 years and with a body weight of at least 25 kg and in adolescents with moderate to severe disease. Taltz reduces the signs and symptoms of the disease.

Psoriatic arthritis

Taltz is used to treat a condition called “psoriatic arthritis” in adults, an inflammatory disease of the joints, often accompanied by psoriasis. If you have psoriatic arthritis you will first be given other medicines. If you do not respond well enough to these medicines or in case of intolerance, you will be given Taltz to reduce the signs and symptoms of the disease. Taltz can be used alone or with another medicine named methotrexate.

Axial spondyloarthritis

Taltz is used to treat adults with an inflammatory disease primarily affecting the spine which causes inflammation of the spinal joints, called axial spondyloarthritis. If the condition is visible using X-rays, it is referred to as “radiographic axial spondyloarthritis”; if it occurs in patients with no visible signs on X-rays, it is referred to as “non- radiographic axial spondyloarthritis”. If you have axial spondyloarthritis you will first be given other medicines. If you do not respond well enough to these medicines, you will be given Taltz to reduce the signs and symptoms of the disease, reduce inflammation and improve your physical function.

How Taltz works

Taltz contains the active substance ixekizumab. 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 for plaque psoriasis will benefit you by improvements of skin clearance and reducing your symptoms such as scaling, itching and pain. Using Taltz for psoriatic arthritis and Axial Spondyloarthritis 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.

Before you use Taltz

- When you must not use it

- If you are allergic to ixekizumab or any of the other ingredients of this medicine (see **Product Description** section).
- If you have an infection which your doctor thinks is important (for example, active tuberculosis).

- Before you start to use it

Talk to your doctor before using Taltz:

- if you currently have an infection or if you have long-term or repeated infections.
- if you have an inflammation disease affecting the gut named Crohn’s disease.
- if you have an inflammation of the large intestine named ulcerative colitis.
- if you 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, diarrhoea, 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.

Children and adolescents

Do not use this medicine for the treatment of plaque psoriasis in children under 6 years of age because it has not been studied in this age group.

Do not use this medicine for the treatment of psoriatic arthritis in children and adolescents under 18 years of age because it has not been studied in this age group.

Pregnancy and lactation

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. It is preferable to avoid the use of Taltz in 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 breast-feeding or are planning to breast-feed, talk to your doctor before using this medicine. You and your doctor should decide if you will breast-feed or use Taltz. You should not do both.

- Taking other medicines

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.

How to use Taltz

- How much to use

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

Plaque psoriasis in adults

- 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.

Plaque psoriasis in children (age 6 years and above and at least 25 kg body weight) and in adolescents

- The recommended dose given by subcutaneous injection in children is based on the following weight categories:

Children's body weight greater than 50 kg:

- Recommended starting dose (Week 0): 160 mg (2 pens)
- Recommended dose every 4 weeks (Q4W) thereafter: 80 mg (1 pen)

Children's body weight 25 to 50 kg:

- Recommended Starting Dose (Week 0): 80 mg (1 pen)
- Recommended Dose every 4 weeks (Q4W) thereafter: 40 mg (dose preparation required if the 40 mg syringe is not available)

If the 40 mg pre-filled syringe is not available, ixekizumab doses of 40 mg must be prepared and administered by a qualified healthcare professional using the commercial Taltz 80 mg pre-filled syringe.

Use the Taltz 80 mg pre-filled pen only in those children that require a dose of 80 mg. Do not use the Taltz 80 mg pre-filled pen for the preparation of the 40 mg dose.

Taltz is not recommended for use in children with a body weight below 25 kg.

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 (one injection) every 4 weeks.

For other psoriatic arthritis patients

- The first dose is 160 mg (two 80 mg injections) 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 (radiographic and non-radiographic)

- 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.

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.

- When to use it

Always use this medicine exactly as your doctor or nurse has told you. Check with your doctor, nurse or pharmacist if you are not sure how to use this medicine.

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

For use in children with a body weight of 25-50 kg ixekizumab doses of 40 mg must be prepared and administered by a qualified healthcare professional.

Use the Taltz 80 mg pre-filled pen only in those children that require a dose of 80 mg and do not require dose preparation.

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.

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

Read the "Instructions for use" for the pen carefully before using Taltz.

- How long to use it

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.

- If you forget to use it

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

- If you use too much (overdose)

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

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

- Things you must not do

You should not stop using Taltz without speaking to your doctor first. If you stop

treatment, symptoms of your disease may come back.

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

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

- Things to be careful of

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 (see **Side Effects** section).

Driving and using machines

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

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.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets 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 (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 (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 (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 (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 (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, diarrhoea, weight loss or blood in the stool (signs of bowel problems)

Rare (may affect up to 1 in 1 000 people)

- fungal infection of the oesophagus (oesophageal candidiasis)
- redness and peeling of the skin (exfoliative dermatitis)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting

Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of Taltz

- **Storage**
Keep out of the reach and sight of children.

Do not use this medicine after the expiry date, which is stated on the pen label and on the outer carton after "EXP".

The expiry date refers to the last day of that month.

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

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

Taltz can be left out of the fridge for up to 5 days at a temperature not above 30 °C.

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.

- **Disposal**
Do not throw away any medicines via wastewater. Ask your doctor, nurse or pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

- **What it looks like**
Taltz is a solution in a clear glass syringe. Its colour may vary from colourless to slightly yellow. The syringe is encased in a disposable, single-dose pen. Pack size of 1 pre-filled pen.

- **Ingredients**
 - Active ingredient
Ixekizumab

- Inactive ingredients
 - Sucrose
 - Polysorbate 80
 - Water for injections
 - In addition, sodium hydroxide may have been added for pH adjustment (see section "Taltz contains sodium" and "Taltz contains polysorbate").

- **MAL number(s):**
MAL25086005AZ

Manufacturer

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

Product Registration Holder

Zuellig Pharma Sdn Bhd
No. 15, Persiaran Pasak Bumi, Seksyen U8, Perindustrian Bukit Jelutong, 40150 Shah Alam Selangor, Malaysia.

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