Package leaflet: Information for the patient

Taltz 80 mg solution for injection in pre-filled syringe
ixekizumab

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- 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.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Taltz is and what it is used for

Taltz contains the active substance ixekizumab.

Taltz is intended for the treatment of the inflammatory diseases described below:
- Plaque psoriasis in adults
- Plaque psoriasis in children from the age of 6 and with a body weight of at least 25 kg and in adolescents
- Psoriatic arthritis in adults
- Radiographic Axial Spondyloarthritis in adults
- Non-radiographic Axial *S*pondyloarthritis in adults

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.

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.

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

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.

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.

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.

2. What you need to know before you use Taltz

Do not use Taltz
- if you are allergic to ixekizumab or any of the other ingredients of this medicine (listed in section 6). If you think you may be allergic, ask your doctor for advice before using Taltz.
- if you have an infection which your doctor thinks is important (for example, active tuberculosis).

Warnings and precautions
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 inflammatory 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.

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 section 4.

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.

Other medicines and Taltz
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 breast-feeding
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 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 adequate 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 can breast-feed or use Taltz. You should not do both.

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, that is to say essentially "sodium-free".

3. How to use Taltz

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.

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.

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

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

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

<u>Plaque psoriasis in adults</u>
- The first dose is 160 mg (2 syringes 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 syringe) at weeks 2, 4, 6, 8, 10, and 12. From week 12, you will use an 80 mg dose (1 syringe**)** 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	**Recommended starting dose (week 0)**	**Recommended dose every 4 weeks (Q4W) thereafter**
Greater than 50 kg	160 mg (2 syringes)	80 mg (1 syringe)
25 to 50 kg	80 mg (1 syringe)	40 mg (dose preparation required)

40 mg preparation of ixekizumab in children
Ixekizumab doses of 40 mg must be prepared and administered by a qualified healthcare professional. 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 syringes 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 syringe) at weeks 2, 4, 6, 8, 10, and 12. From week 12, you will use an 80 mg dose (1 syringe) every 4 weeks.

For other psoriatic arthritis patients
- The first dose is 160 mg (2 syringes 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 syringe) every 4 weeks.

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

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

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

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

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

4. Possible 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
- 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)

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Taltz

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the syringe 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 to 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 ºC.

Do not use this medicine if you notice that the syringe 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 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.

6. Contents of the pack and other information

What Taltz contains
- The active substance is ixekizumab.
  Each pre-filled syringe contains 80 mg of ixekizumab in 1 ml solution.
- The other ingredients are sucrose; polysorbate 80; water for injections. In addition, sodium hydroxide may have been added for pH adjustment.

What Taltz looks like and contents of the pack
Taltz is a solution in a clear glass syringe. Its colour may vary from colourless to slightly yellow.

Pack sizes of 1, 2, 3 pre-filled syringes. Not all pack sizes may be available in your country.

Marketing Authorisation Holder
Eli Lilly and Company (Ireland) Limited, Dunderrow, Kinsale, Co. Cork, Ireland.

Manufacturer
Eli Lilly Italia S.p.A.,Via Gramsci 731/733, 50019, Sesto Fiorentino (FI), Italy.

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

United Kingdom (Great Britain)
Eli Lilly and Company Limited
Tel: + 44-(0) 1256 315000

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The following information is intended for medical or healthcare professionals only:

<u>40 mg preparation of ixekizumab for children 25-50 kg body weight</u>

Ixekizumab doses of 40 mg must be prepared and administered by a qualified healthcare professional. Use only the Taltz 80 mg solution for injection in pre-filled syringe when preparing the prescribed 40 mg paediatric doses.

1. Expel the entire contents of the pre-filled syringe into a sterile, clear glass vial. DO NOT shake or swirl the vial.
2. Use a 0.5 ml or 1 ml disposable syringe and sterile needle to withdraw the prescribed dose (0.5 ml for 40 mg) from the vial.
3. Change the needle and use a 27-gauge, sterile needle to inject the patient. Discard any unused ixekizumab in the vial.

The prepared ixekizumab must be administered within 4 hours of puncturing the sterile vial at room temperature.