

Package leaflet: Information for the patient

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

ixekizumab

The name of your medicine is Taltz 80 mg solution for injection in pre-filled syringe but will be referred to as Taltz throughout this leaflet.

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
2. What you need to know before you use Taltz
3. How to use Taltz
4. Possible side effects
5. How to store Taltz
6. Contents of the pack and other information

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 Spondyloarthritis 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.

Plaque psoriasis in adults

- 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 °C.

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.

If this medicine becomes discoloured or shows any other signs of deterioration, please contact your pharmacist who will advise you on what to do.

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.

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

Package leaflet: Information for the patient

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

ixekizumab

40 mg preparation of ixekizumab for children 25-50 kg body weight

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.



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 size of 1 pre-filled syringe.

Product Licence Holder and Manufacturer

Procured from within the EU by the Product Licence holder Orifarm UK Ltd., Ground Floor Suite A2, Breakspear Park, Breakspear Way, Hemel Hempstead, HP2 4TZ, UK

For any information about this medicine, please contact the Product Licence Holder on

www.orifarm.com/uk

Or phone: (+44) 1923 204333

Repacked by Orifarm Supply s.r.o., Palouky 1366, 253 01 Hostivice, Czech Republic

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

Taltz 80 mg solution for injection in pre-filled syringe

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POM

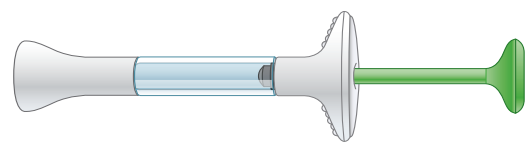
Leaflet revision date: 28/08/2025

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read?
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suitable for you.



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

ixekizumab



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

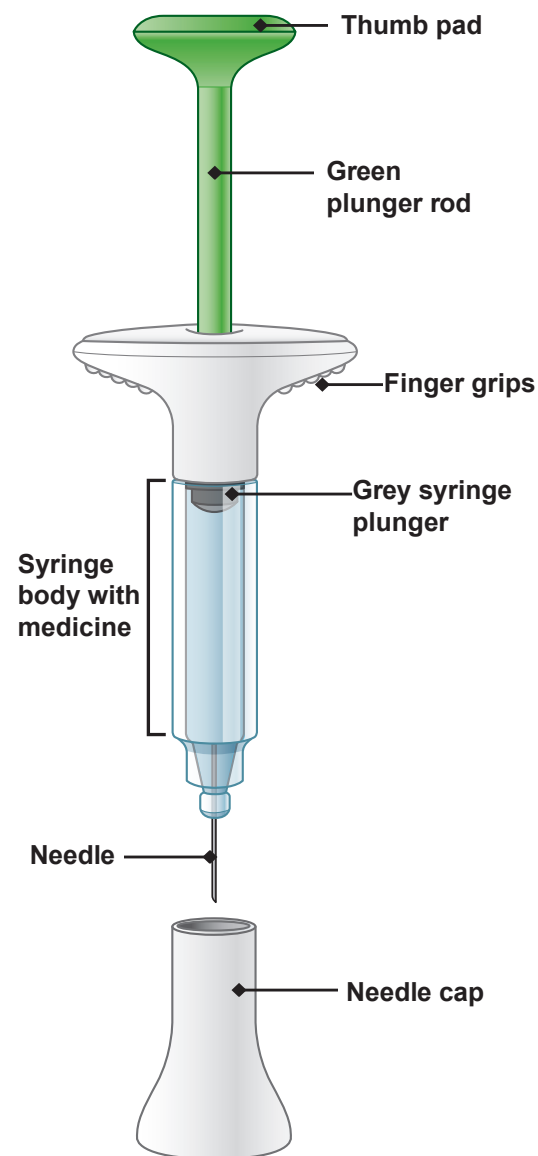
Before using your pre-filled syringe: Important points to know

- Before you use the Taltz pre-filled syringe, read and carefully follow all the step-by-step instructions. Keep the Instructions for use and refer to them as needed.
- The pre-filled syringe contains 1 dose of Taltz. The syringe is for ONE-TIME USE ONLY.
- The syringe must not be shaken.
- Your doctor, pharmacist or nurse may help you decide where on your body to inject your dose.
- Read the Taltz Package Leaflet inside this box to learn more about your medicine.

INSTRUCTIONS FOR USE

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

Guide to the parts



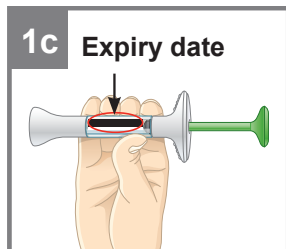
1 GET READY

1a Take the syringe from the refrigerator. Leave the needle cap on the syringe until you are ready to inject. **Wait 30 minutes** to let the syringe 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 syringes



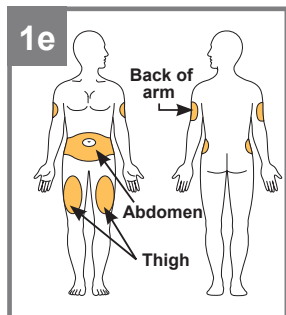
1c Expiry date Inspect the pre-filled syringe for damage to the outside. Leave the needle cap on the syringe until you are ready to inject. Check the label. Make sure the name Taltz appears on the label.

The medicine inside should be clear. Its colour may vary from colourless to slightly yellow.

If you see any of the following, **DO NOT USE** the syringe, 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.

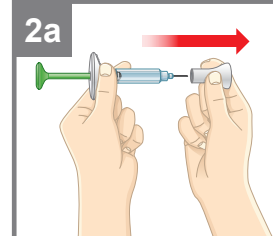
You may inject in your abdomen (stomach area), in your thigh, or in the back of your arm. To inject in your arm, you will need someone to help you.

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).

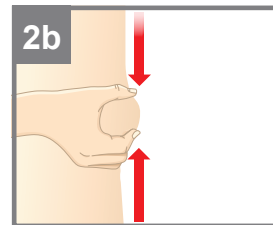
Alternate your injection sites. DO NOT inject in the exact same spot every time. For example, if your last injection was in your left thigh, your next injection should be in your right thigh, your abdomen, or the back of either arm.

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

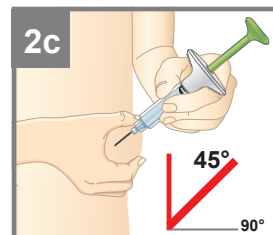
2 INJECT



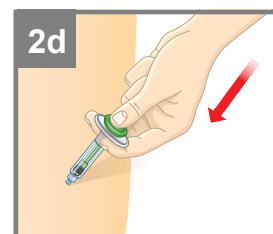
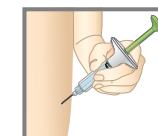
2a Pull the needle cap off and throw it away. **DO NOT** put the needle cap back on—you could damage the needle or injure yourself by accident. **DO NOT** touch the needle.



2b Gently pinch and hold a fold of skin where you will inject.



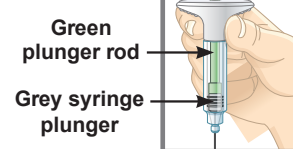
2c Insert the needle at a 45-degree angle. Then gently let go of your skin. Make sure to keep the needle in place.



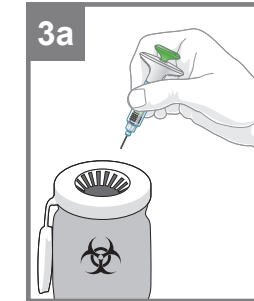
2d Push in the plunger. Slowly push the plunger all the way in until all the medicine is injected. The grey syringe plunger should be pushed all the way to the end of the syringe. Gently remove the needle from your skin.

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.

You should see the green plunger rod showing through the syringe body when the injection is complete.



3 FINISH



3a Dispose of the pre-filled syringe. **DO NOT** put the needle cap back on. Dispose of the syringe in a sharps container or as directed by your doctor, pharmacist or nurse.

When you dispose of syringes and the sharps container:

- Dispose of the syringe 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 syringe, call your doctor, pharmacist or nurse.
- If you have vision problems, **DO NOT** use the pre-filled syringe without help from a person trained to use it.
- **DO NOT** share or reuse your Taltz pre-filled syringe. You may give or get an infection.
- Keep the syringe out of the reach and sight of children.
- If you do not have a sharps container, ask your doctor, pharmacist or nurse about where you can get one.

Commonly asked questions

Q. What if I see air bubbles in my syringe?
A. It is normal to sometimes have air bubbles in the syringe. Taltz is injected under your 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 needle 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 cannot push in the plunger?
A. If the plunger is stuck or damaged:

- **DO NOT** continue to use the syringe.
- Remove the needle from your skin.

Q. How can I tell if my injection is complete?
A. When your injection is complete:

- The green plunger rod should show through the body of the syringe.
- The grey syringe plunger should be pushed all the way to the end of the syringe.

Q. What if the syringe is left at room temperature for longer than 30 minutes?
A. If needed, the syringe 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 package leaflet inside this box to learn more about your medicine.