

Package leaflet: Information for the patient

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

ixekizumab

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

<p>Read all of this leaflet carefully before you start using this medicine because it contains important information for you.</p> <ul style="list-style-type: none">– 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.
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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.

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.

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.

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 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	Recommended starting dose (week 0)	Recommended dose every 4 weeks (Q4W) thereafter
Greater than 50 kg	160 mg (2 pens)	80 mg (1 pen)
25 to 50 kg	80 mg (1 pen)	40 mg (dose preparation required)

Ixekizumab doses of 40 mg must be prepared and administered by a qualified healthcare professional using the commercial Taltz 80 mg/1 ml 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 (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.

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 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 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 pen 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.

6. Contents of the pack and other information

What Taltz contains

- The active substance is ixekizumab. Each pre-filled pen 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.

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

Pack size of 1 pre-filled pen.

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

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POM

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Is this leaflet hard to see or read?
Call +45 63 95 27 00
to obtain the leaflet in a format suitable for you.

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

ixekizumab



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

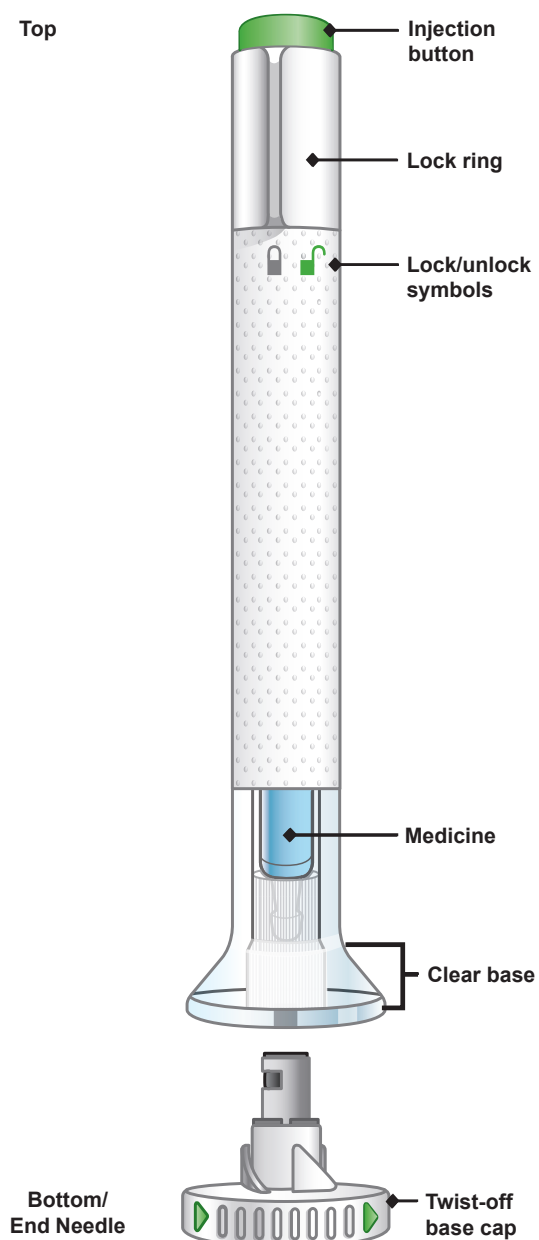
Before using your pre-filled pen: Important points to know

- 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 Package 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

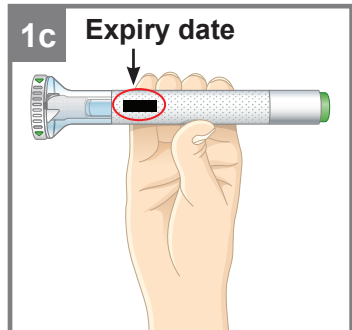
1a Take the pre-filled pen from the refrigerator. Leave the base cap on until you are ready to inject. **Wait 30 minutes** to let the pre-filled pen warm to room temperature before you use it.



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 Expiry date

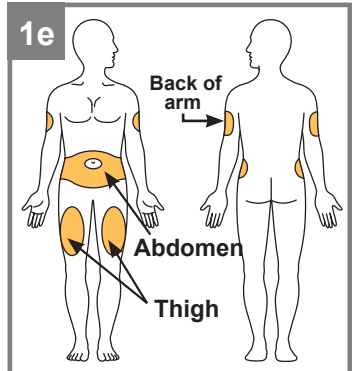
Inspect the pre-filled pen. Check the label. Make sure the name Taltz appears on the label.

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 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.

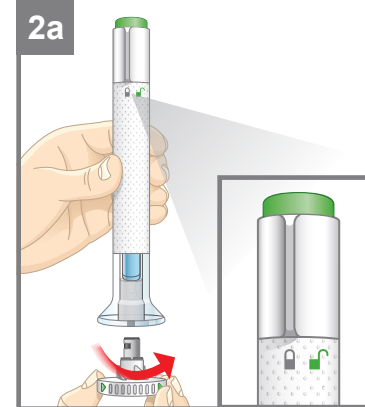
You may inject in your abdomen (stomach area), in your thigh, or in the back of your arm. To inject in your arm, you will need someone to help you.

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



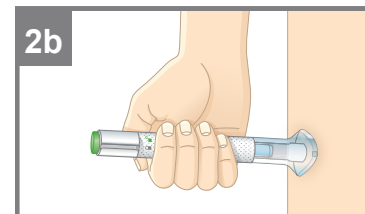
2a

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.

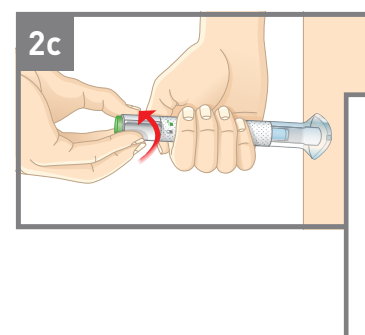
Twist off the base cap.

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.



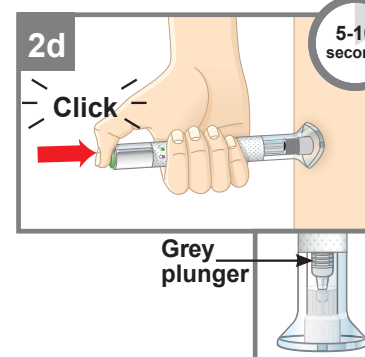
2b

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.**

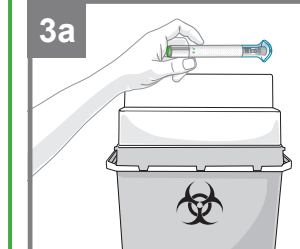
You will also see the grey plunger at the top of the clear base.

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 grey 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 package leaflet inside this box to learn more about your medicine.