

For patients:
Your starting
guide to **Taltz**[®]
(ixekizumab)





ADDITIONAL INFORMATION

This leaflet contains information for patients who have been prescribed Taltz by their doctor and is based on the information provided in the package insert. This brochure is not intended to contain comprehensive information about your medication. For further information about your medication, please consult your doctor or healthcare professional.

Additional information can also be found in the accompanying leaflet with the medication package. Tell your doctor, pharmacist or nurse if you are currently using, have recently used, or may use other medications, both prescription and non-prescription medications, dietary supplements or natural remedies. Your doctor will decide if you can take Taltz together with other medications. You can read more about Taltz in the package insert found inside the packaging or at www.fass.se

BRIEF ABOUT TALTZ

Your doctor has prescribed Taltz to you. Taltz is a biological medication developed to treat moderate to severe plaque psoriasis in adults and children over 6 years, as well as axial spondylitis and psoriatic arthritis in adults.

Plaque psoriasis: Using Taltz improves skin healing and symptoms such as scaling, itching and pain are reduced. However, as with many drugs, the treatment effect varies from person to person.

Axial spondylitis: Taltz is approved for the treatment of axial SpA, a disease in which the pelvic joints and spinal joints can become inflamed and cause pain and stiffness. Taltz reduces these symptoms and improves function.

Psoriatic arthritis: With Taltz, you will experience fewer signs and symptoms of the disease, improved physical function (the ability to perform normal daily activities) and reduced joint damage. However, as with many drugs, the treatment effect varies from person to person. Taltz is intended for long-term treatment. Your doctor or nurse will check you regularly to ensure the treatment has the desired effect.

BEFORE YOU START YOUR TREATMENT WITH TALTZ

Talk to your doctor, nurse or pharmacist before using Taltz:

- if you have an ongoing infection or if you have had long-term or repeated infections
- if you have Crohn's disease
- if you have ulcerative colitis
- if you receive any other treatment for psoriasis (e.g. immunosuppressive agents or treatment with ultraviolet light) or for psoriatic arthritis.

If you're not sure if any of the above applies to you, please speak to your doctor or nurse before using Taltz.

HOW IS TALTZ ADMINISTERED?

Taltz is given as an injection under the skin (subcutaneous injection). The first few times you will receive the injection from healthcare professionals, but once you are confident, you can administer the injection yourself at home. You'll decide with your healthcare team when you're ready to self-inject at home.

If you do not feel safe administering the injection yourself, a relative can be trained in injection technique to help you.

Regardless of who gives you the injection, it is important to carefully follow the instructions of your healthcare professional. This also applies when it comes to the dosage of Taltz and duration of your treatment.

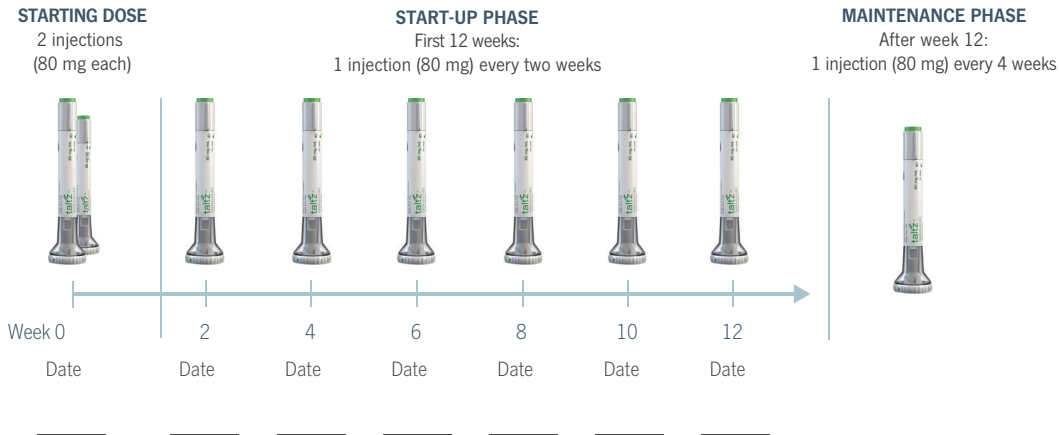
TIPS FOR REMEMBERING YOUR MEDICATION

- **Mark your calendar with the date of your next dose.**
- **Tear off the dosage chart on the next page and place it somewhere visible at home.**

TIP!
Tear out this page and
place it somewhere
visible at home

DOSAGE – plaque psoriasis and psoriatic arthritis with moderate to severe plaque psoriasis

You should take Taltz every two weeks for the first 12 weeks and then every four weeks*.
Record the dates for when you should take your next injection to make it easier to remember.



* If your doctor has given you other instructions about when to take your medication, you should always follow your doctor's recommendation.

DOSAGE – psoriatic arthritis

TIP!
Tear out this page and
place it somewhere
visible at home

You must take Taltz every four weeks after the starting dose*.

Record the dates for when you should take your next injection to make it easier to remember.

STARTING DOSE

2 injections
(80 mg each)



MAINTENANCE PHASE

subsequent doses:
1 injection (80 mg) every 4 weeks



Week 0

4

8

12

Date:

Date:

Date:

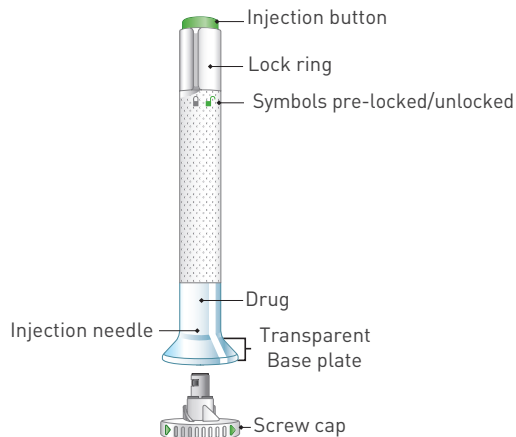
Date:

* If your doctor has given you other instructions about when to take your medication, you should always follow your doctor's recommendation.

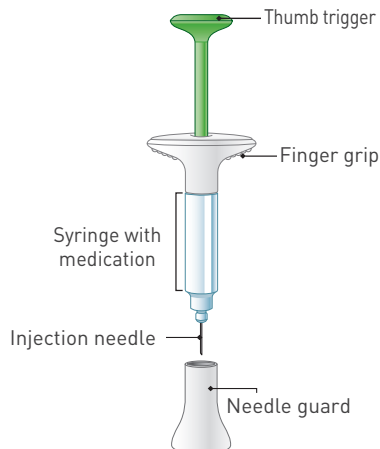
PEN OR SYRINGE?

The Taltz injection can be administered in two forms: a pre-filled pen or a pre-filled syringe. You will decide which one suits you best in consultation with the healthcare staff.

TALTZ PEN



TALTZ SYRINGE



HOW TO ADMINISTER TALTZ

The pre-filled pen and the pre-filled syringe are administered in different ways.

First, decide in consultation with healthcare personnel which type to use. Then, follow the step-by-step guide for the pen or syringe.

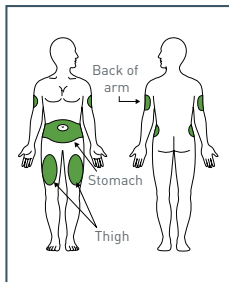
TALTZ PEN: STEP BY STEP

Read more in the leaflet that found in the packaging.



1. PREPARATION

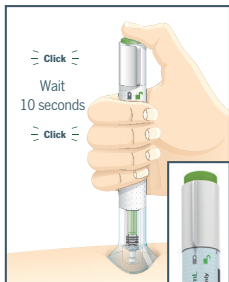
- **Take the pre-filled pen out of the refrigerator and wait 30 minutes until the pen is at room temperature.**
Never use any type of heat source to heat the medication.
- **Check the pen.**
If the pen looks damaged, if the medication is cloudy, distinctly brown or contains small particles or if the expiry date has passed, the pen should NOT BE USED.
- **Wash your hands before proceeding to step two.**



2. SELECT INJECTION SITE

- **You can administer the injection in the stomach, thigh or back of the upper arm.**
If you are injecting in the arm, someone must help you. Do not inject in areas where the skin is fragile, damaged, reddened or hardened or where you have scars or stretch marks. Do not inject within 2.5 centimetres of the belly button.
- **Change the injection site.**
Do not inject in exactly the same spot each time. For example, if your last injection was in the left thigh, the next injection should be in the right thigh, stomach or back of the arm.

You can find the expiry date on the label of the pen and on the box after “EXP”.
The expiration date is the last day of the month.



3. ADMINISTER THE INJECTION

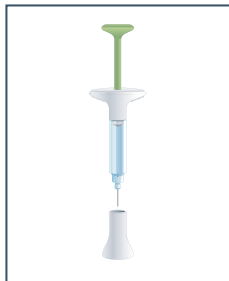
- **Clean the skin with an alcohol wipe.**
Allow the injection site to air dry before injecting the medication.
- **Make sure the locking ring is in the “locked” position and then unscrew the cover (bottom plate).**
- **Place the transparent base plate firmly flat against the skin. Then turn the locking ring to the “unlocked” position.**
- **Press the green injection button.**
There will be a loud click.
- **Continue to hold the clear flat part close to the skin.**
After about 5-10 seconds, another loud click will be heard.
This means the injection is complete.

4. DISPOSAL OF THE PEN

- **Place the pen in a needle box or follow the instructions of your healthcare professional.**
DO NOT put the cap back on - you could accidentally prick yourself.

TALTZ SYRINGE: STEP BY STEP

Read more in the leaflet that you found in the packaging.



1. PREPARATION

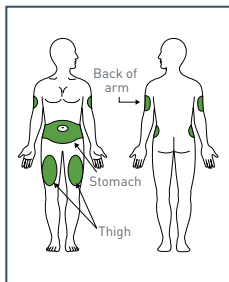
- Take the pre-filled syringe out of the refrigerator and wait 30 minutes until the syringe is at room temperature.

Never use any type of heat source to heat the medication.

- Check the syringe

If the syringe looks damaged, if the medication is cloudy, distinctly brown or contains small particles or if the expiry date has passed, the syringe should NOT BE USED.

- Wash your hands before proceeding to step two.



2. SELECT INJECTION SITE

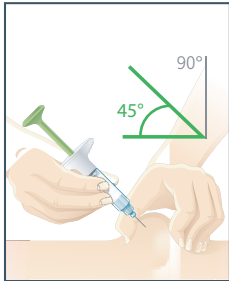
- You can administer the injection in the stomach, thigh or back of the upper arm.

If you are going to inject in the arm, someone must help you. Do not inject in areas where the skin is fragile, damaged, reddened or hardened or where you have scars or stretch marks. Do not inject within 2.5 centimetres of the belly button.

- Change the injection site.

Do not inject in exactly the same spot each time. For example, if your last injection was in the left thigh, the next injection should be in the right thigh, stomach or back of the arm.

You can find the expiry date on the syringe label and on the carton after “EXP”.
The expiration date is the last day of the month.



3. ADMINISTER THE INJECTION

- Clean the skin with an alcohol wipe.
- Remove the needle cover.
Be careful **NOT** to touch the needle.
- Gently grasp the skin at the injection site.
- Insert the needle at a 45 degree angle. Then gently release the skin. Make sure to keep the needle in place.
- Slowly push the syringe plunger all the way down until all the medication is injected.
- Carefully pull the needle out of the skin.



4. DISPOSAL OF THE SYRINGE

- Place the syringe in a needle box or follow the instructions of your healthcare professional.
DO NOT put the cap back on - you could accidentally prick yourself.

SIDE EFFECTS

You can help by reporting any side effects you may experience. Information on how to report side effects can be found at the end of section 4 in the package insert.

Like all medications, Taltz can cause side effects, but not all users experience them. Contact your doctor or nurse if you experience side effects during your treatment with Taltz.

If a side effect worsens, or if you experience a side effect that is not mentioned in this information, you should immediately contact your doctor.

You can read more about Taltz and possible side effects in the package insert that comes with the medication package. Alternatively, you can read more at www.fass.se.

Very common side effects

(may affect 1 in 10 people):

- Upper respiratory tract infections with symptoms such as sore throat and stuffy nose.
- Injection site reactions (e.g. skin redness, pain).

Common side effects

(may affect 1 in 10 people):

- Ulcers
- Nausea: feeling queasy or feeling sick to your stomach
- Tinea infection: Ringworm
- Herpes simplex (mucocutaneous): Cold sores or fever blisters
- Oropharyngeal pain: Throat pain

Serious side effects

Stop using Taltz and tell your doctor or get medical help right away if you experience any of the following side effects. Your doctor will decide if and when you can restart the treatment.

Possible serious infection (may affect 1 in 100 people) - signs may include:

- Fever, flu-like symptoms, night sweats
- Tiredness or shortness of breath, cough that does not go away
- Warm, reddened and sore skin, or a painful rash with blisters.

Serious allergic reaction (may affect 1 in 1,000 people) - signs may include:

- Difficulty breathing or swallowing
- Low blood pressure, which can cause dizziness or lightheadedness
- Swelling of the face, lips, tongue or throat
- Severe itching of the skin, with red rashes or raised nodules.

THREE STORAGE RULES

It is important that you store your medication correctly.
Follow these three simple rules and your medication is in good hands.

1. Keep your medication out of the reach of children.

2. Store the medication in the refrigerator.

Taltz should be stored at a temperature between 2 °C and 8 °C. However, the medication can temporarily be stored at room temperature (at a maximum of 30 °C) for up to five days. The medication must not be frozen.

3. Store the medication in its original packaging.

The packaging protects the medication from light.

QUESTIONS AND ANSWERS

What do I do if I have taken too much medication?

You must inform the healthcare staff immediately.

This also applies if you took the injection before the scheduled time.

What do I do if I forget to take my medicine?

If you have missed a dose, contact the healthcare staff.

What happens if I stop taking my medication?

If you stop taking your medication, your symptoms may return. Do not stop your treatment without consulting the healthcare staff.

There is a drop at the very end of the needle when I remove the needle cover, is this normal?

A drop of liquid on the tip of the needle is normal. It won't hurt you or affect your dose.

Can I take Taltz if I am pregnant or trying to become pregnant?

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, consult your doctor before using this medication. If you are a woman of childbearing age, it is recommended that you avoid becoming pregnant and you must use appropriate birth control while using Taltz and for at least 10 weeks after the last dose of Taltz.

There is limited information about the use of Taltz in pregnant women. As a precaution, Taltz should not be used during pregnancy.

Can I drive while being treated with Taltz?

The medication is unlikely to affect your ability to drive or operate machinery.

Where can I find more information about psoriasis, axial spondylitis, and psoriatic arthritis?

You can find more information about psoriasis on the Psoriasis Association's website: **www.psoriasisforbundet.se**, as well as axial spondylarthritis and psoriatic arthritis on The Rheumatism Association website: **www.reumatiker.se**

DO YOU HAVE MORE QUESTIONS?

Ask the healthcare staff or contact

Lilly's Medical Information by phone: 08-737 88 00 (office hours) or
email: scan_medinfo@lilly.com

MEDICAL STAFF CONTACT INFORMATION

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Warnings and precautions: Talk to your doctor:

- if you have an ongoing infection or if you have had long-term or repeated infections
- if you have an inflammatory disease of the gastrointestinal tract called Crohn's disease
- if you have an inflammatory disease of the large intestine called ulcerative colitis
- if you are receiving any other treatment for psoriasis (e.g. immunosuppressive agents or ultraviolet light therapy) or against psoriatic arthritis.

Stop using Taltz and tell your doctor or seek medical attention immediately if you notice stomach cramps and pain, diarrhoea, weight loss or blood in the stool (possible signs of bowel problems).

Taltz should not be used at the same time as live vaccines.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding, or think you may be pregnant or plan to have a baby, consult your doctor before using this medication. It is best to avoid using Taltz during pregnancy. The drug's effect on pregnant women is unknown. If you are a woman and of childbearing age, it is recommended that you avoid becoming pregnant and you must use appropriate birth control while using Taltz and for at least 10 weeks after the last dose of Taltz.

If you are breastfeeding or plan to breastfeed, talk to your doctor before using this medication. You and your doctor must decide whether you can breastfeed or use Taltz. You should not do both.

For further information see www.fass.se

Read the leaflet carefully before you start using this medication.

Reporting of side effects and complaints

If you experience side effects, talk to your doctor or other healthcare professional. This also applies to any side effects that are not mentioned in the leaflet. You can report side effects directly via the Swedish Medicines Agency's website www.lakemedelsverket.se. Side effects and complaints can also be reported to Lilly. Call Lilly's medical information on **+46 (0)8 737 88 00** or send an email to **scan_medinfo@lilly.com**. By reporting side effects, you can contribute more information about drug safety.

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