



## **QUESTIONS AND ANSWERS ABOUT YOUR THERAPY WITH TALTZ®**

Information for patients with axial spondyloarthritis  
and psoriatic arthritis



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## Information about Taltz®

### When is Taltz® used?

**In adults**, Taltz® is used to treat axial spondyloarthritis and psoriatic arthritis.

**In children**, Taltz® is used to treat juvenile psoriatic arthritis (an inflammatory disease of the joints that is often associated with psoriasis) and enthesitis-associated arthritis (an inflammatory disease of the joints that often affects the pelvis and spine) in children aged 6 years and older who weigh at least 25 kg.

If you or your child have one of the conditions mentioned above, you will usually have been given other medications first. If these medications have not provided sufficient improvement for you or your child, you will be given Taltz® to alleviate the symptoms of the condition.

Taltz® is used to treat axial spondyloarthritis and psoriatic arthritis. If you have either of these conditions, you will usually have been given other medications first. If these medications have not offered sufficient relief, you will be given Taltz® to alleviate the symptoms of the disease. Taltz® can be used alone or in combination with other medications.

When treating axial spondyloarthritis, a combination of exercise and drug therapy should always be sought. Please discuss this point with your treating specialist.

### What is Taltz® and how does it work?

Taltz® contains the active substance ixekizumab. Ixekizumab belongs to the class of drugs known as interleukin (IL-17A) inhibitors. Interleukins are the body's own messenger substances. The messenger substance IL-17A plays a key role in the inflammatory process of axial spondyloarthritis and psoriatic arthritis. Taltz® can bind to this messenger substance and thus inhibits its function. In this way, Taltz® counteracts inflammation and the resulting symptoms of the disease.

### Why is Taltz® injected?

Taltz® cannot be taken as a tablet because it is an antibody. Antibodies are large protein molecules that, if taken by mouth, would be digested in the stomach and thus become ineffective. By administering the active substance with an injection, it can enter the bloodstream directly and then take effect.



## How should I store Taltz®?

Please store your prefilled pens or prefilled syringes in the refrigerator at 2–8°C. It is imperative to ensure that Taltz® does not freeze. If this happens, you will no longer be able to use the pen or syringe. Store in the original packaging in order to protect the contents from light. Taltz® can be stored unrefrigerated for up to 5 days at a maximum temperature of 30°C.

## What should I do if I forget an injection?

If you miss a Taltz® injection, please talk to your doctor.

## How long does therapy with Taltz® last?

Axial spondyloarthritis and psoriatic arthritis are chronic, i.e. long-term diseases that are currently incurable but can usually be treated effectively. To ensure that the therapy has the desired effect, you should make sure that you follow the treatment plan prescribed by your doctor exactly. If the Taltz® therapy works, you will notice an improvement in your symptoms. However, you should continue taking your medicine unless your doctor tells you otherwise. In order to permanently reduce disease activity, it is important that Taltz® is used regularly and over the long term.

## How long will it take until I notice that I am feeling better?

Everyone has their own medical history. Therefore, it cannot be predicted exactly how each individual will respond to the treatment with Taltz® or how quickly the drug will begin to work.

However, it is known that typical symptoms in people with axial spondyloarthritis and psoriatic arthritis who used Taltz® as recommended and who responded to treatment improved within the first one to twelve weeks of treatment. For example, patients with psoriatic arthritis had fewer skin problems, less pain, and their joints were more mobile. In cases of axial spondyloarthritis, patients had less back pain and morning joint stiffness and were more mobile and less tired.



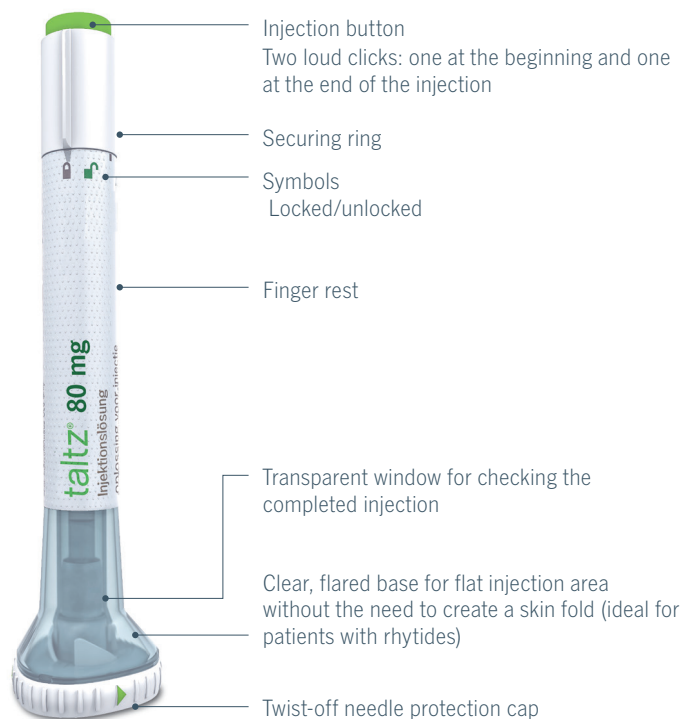
# Prefilled pen

## How do I use my Taltz® prefilled pen correctly?

Before using the Taltz® prefilled pen, read the instructions for use carefully and follow all instructions exactly step by step.

Each prefilled pen contains 1 dose of Taltz®. The prefilled pen is intended **FOR SINGLE USE ONLY**. The prefilled pen must not be shaken.

Please note that there are no alcohol swabs included in the package. You can request alcohol swabs and a puncture-proof container for your therapy with Taltz® free of charge from our Medical Information service by calling 06172 273-2222.



## 1. Preparation



**Take the prefilled pen out of the refrigerator. Wait 30 minutes** for the prefilled pen to reach room temperature before using it.



Do **NOT** use heat sources such as a microwave, hot water or direct sunlight to warm the medicinal product.

### Have everything you need ready for your injection:

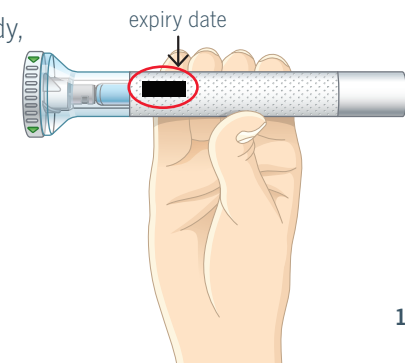
- 1 alcohol swab
- 1 cotton ball or a piece of gauze

### Check the prefilled pen:

Check the label. Make sure Taltz® is on the label. The medicinal product in the prefilled pen must be clear. The colour can vary from colourless to slightly yellowish.

If you notice any of the following, **DO NOT USE** the prefilled pen and dispose of it as described in point 3:

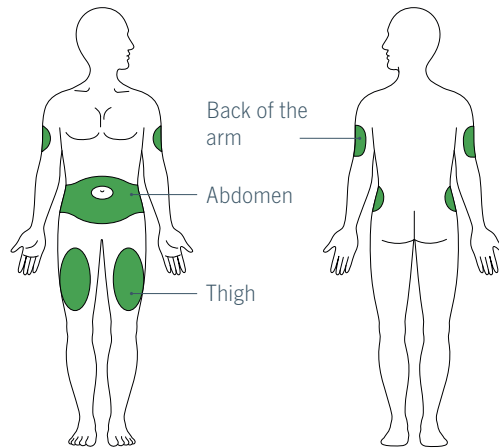
- The expiry date has passed.
- The prefilled pen looks damaged.
- The medicinal product is cloudy, distinctly brown or shows small particles.



Wash your hands before injecting the medicinal product.

### Choose your injection site

You can inject into your abdomen, your thigh, or the back of your arm. You will need help giving the injection into your arm.



**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 1 inch (2.5 cm) of the belly button.

### Vary the injection sites:

Do **NOT** inject more than once in exactly the same place. For example, if your last injection was in your left thigh, the next injection should be in your right thigh, your abdomen, or the back of an arm.

### Prepare your skin:

Clean the skin with an alcohol swab. Allow the injection site to air dry before injecting the medicinal product.

## 2. Injection

- 1** Make sure the locking ring is in the “Locked” position. Leave the needle cap on the pen until you are ready to inject. Do **NOT** touch the needle.

**Unscrew the needle cap.** Discard the protective cap. Do not put the needle cap back on – this might damage the needle or you could accidentally injure yourself.

- 2** Place the lower part of the prefilled pen flat and firmly against your skin at the injection site. Turn the locking ring to the “Unlocked” position.

- 3** You are now ready for the injection. **Press and hold the green injection button.** You will hear a loud click.

**Keep pressing the transparent lower part of the prefilled pen firmly against your skin.** About 5-10 seconds after the first click, you will hear a second loud click. **The second loud click tells you that the injection is complete.** You will also see the grey piston at the top of the transparent lower part.

- 4** Remove the prefilled pen from your skin. The needle retracts on its own.

Press a cotton ball or piece of gauze onto the injection site. Do **NOT** rub the injection site as this may cause bruising. Light bleeding is normal.



### 3. Ending

- Do **NOT** put the needle cap back on the needle.
- After use, dispose of the prefilled pen in a puncture-proof container or as instructed by your doctor, pharmacist or nurse.



## Frequently asked questions about the prefilled pen

### What do I do if I discover air bubbles in my prefilled pen?

Air bubbles in the prefilled pen are normal. Taltz<sup>®</sup> is injected under the skin (subcutaneous injection). Air bubbles are not a problem with this type of injection. They are harmless and do not affect your dosage.

### What do I do if there is a drop of liquid on the needle tip after I remove the needle cap?

It is okay if you see a drop of liquid at the needle tip. It will not harm you and will not affect your dosage.

### What do I do if I unlocked the prefilled pen and pressed the green injection button before removing the needle cap?

Do not remove the needle cap. Contact your doctor, pharmacist or nurse.

### Do I have to keep the green injection button pressed until the injection is completely finished?

This is not necessary, but it may help you press the prefilled pen evenly and firmly against your skin.

### What do I do if the needle is not retracted after the injection?

Do not touch the needle and do not put the needle cap back on. Dispose of the prefilled pen in a sealable, puncture-proof safety container. A puncture-proof container can be requested from the manufacturer Lilly by calling 06172 273-2222. Contact your doctor, pharmacist or nurse.

### What do I do if I heard more than two clicks while performing the injection – two loud clicks and one quiet one? Did I receive my entire injection?

Some patients hear a quiet click just before the second loud click. This is quite normal. Do not remove the prefilled pen from your skin until you hear the second loud click.

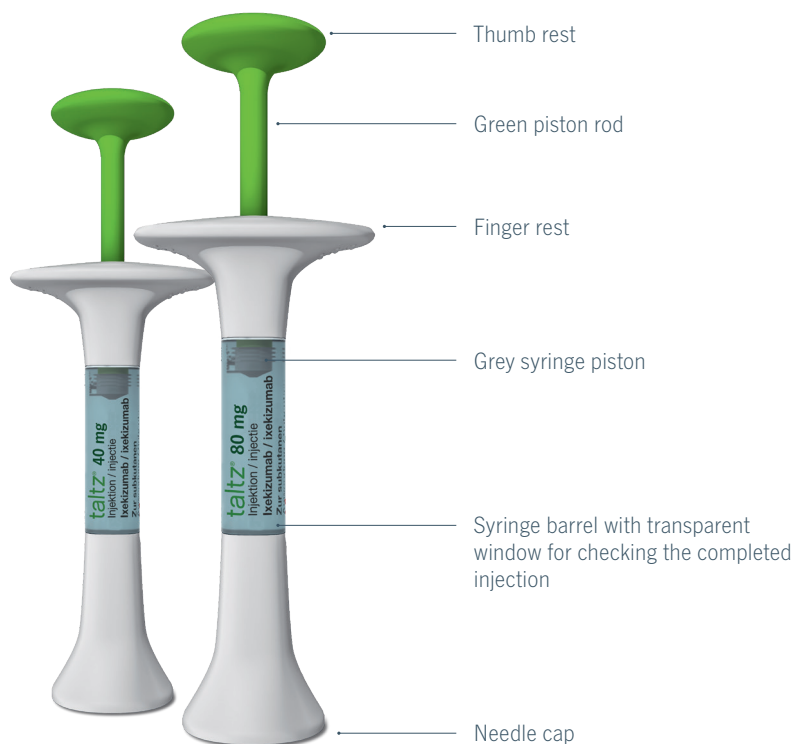
# Prefilled syringe

## How do I use my Taltz® prefilled syringe correctly?

Before using the Taltz® prefilled syringe, read the instructions for use carefully and follow all instructions exactly step by step.

Each prefilled syringe contains 1 dose of Taltz®. The prefilled syringe is intended **FOR SINGLE USE ONLY**. The pre-filled syringe must not be shaken.

Please note that there are no alcohol swabs included in the package. You can request alcohol swabs for your therapy with Taltz® as well as a puncture-proof container for disposal of the prefilled syringe free of charge from our Medical Information service by calling 06172 273-2222.



## 1. Preparation



Take the prefilled syringe out of the refrigerator. Wait 30 minutes for the prefilled syringe to reach room temperature before using it.



Do **NOT** use heat sources such as a microwave, hot water or direct sunlight to warm the medicinal product.

### Have everything you need ready for your injection:

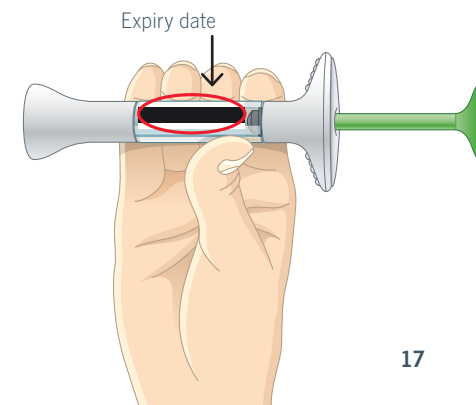
- 1 alcohol swab
- 1 cotton ball or a piece of gauze
- 1 puncture-proof disposal container for prefilled syringes

### Check the prefilled syringe for damage on the outside:

Leave the needle cap on the syringe until you are ready to inject. Check the label. Make sure Taltz® is on the label. The medicinal product in the pre-filled syringe must be clear. The colour can vary from colourless to slightly yellowish.

If you notice any of the following, **DO NOT USE** the prefilled syringe and dispose of it as described in part 3:

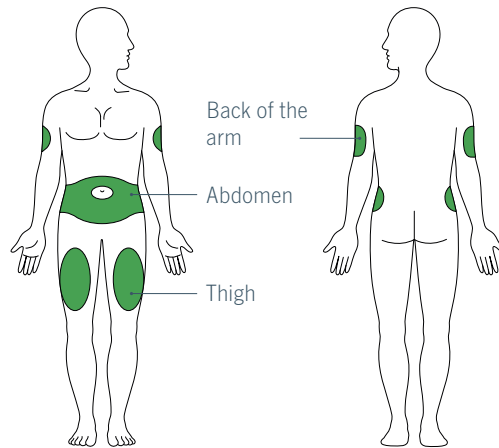
- The expiry date has passed.
- The prefilled syringe looks damaged.
- The medicinal product is cloudy, distinctly brown or shows small particles.



Wash your hands before injecting the medicinal product.

### Choose your injection site

You can inject into your abdomen, your thigh, or the back of your arm. You will need help giving the injection into your arm.



**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 1 inch (2.5 cm) of the belly button.

### Vary the injection sites:

Do **NOT** inject more than once in exactly the same place. For example, if your last injection was in your left thigh, the next injection should be in your right thigh, your abdomen, or the back of an arm.

### Prepare your skin:

Clean the skin with an alcohol swab. Allow the injection site to air dry before injecting the medicinal product.

## 2. Injection

- 1 Remove the needle cap and dispose of it.

DO **NOT** replace the needle cap - this may damage the needle or you may accidentally injure yourself.

**DO NOT** touch the needle.

- 2 Gently make a fold of skin at the injection site and hold it firmly.

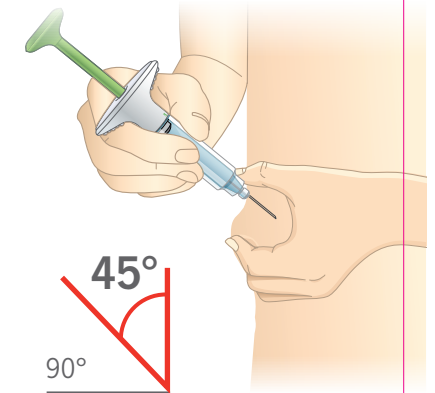
- 3 Insert the needle at a 45 degree angle. Now gently release the fold of skin. Be sure to keep the needle in position.

### Press the plunger.

Push the plunger down slowly and completely until all of the medicinal product is injected. The grey syringe piston must be pushed all the way to the end of the prefilled syringe.

- 4 Pull the needle gently out of your skin. Press a cotton ball or piece of gauze onto the injection site. **DO NOT** rub the injection site as this may cause bruising. Light bleeding is normal.

**After the injection is complete, you should see the green piston rod in the syringe barrel.**



### 3. Ending

- Do **NOT** put the needle cap back on the needle.
- After use, dispose of the prefilled pen in a puncture-proof container or as instructed by your doctor, pharmacist or nurse.



## Frequently asked questions about the prefilled syringe

### What do I do if I discover air bubbles in my prefilled syringe?

Occasional air bubbles in the prefilled syringe are normal. Taltz® is injected under your skin (subcutaneous injection). Air bubbles are not a problem with this type of injection. They are harmless and do not affect your dosage.

### What do I do if there is a drop of liquid on the needle tip after I remove the needle cap?

It's okay if you see a drop of liquid at the needle tip. It will not harm you and will not affect your dosage.

### What do I do if I can't press the plunger?

If the plunger is stuck or defective:

- DO **NOT** continue to use the prefilled syringe.
- Remove the needle from the puncture site.

# Dosage

## Dosage for psoriatic arthritis

There are two different dosing options for **psoriatic arthritis**. The decision as to which dosage regimen is best for you depends on how severely your skin is affected. Your doctor will tell you what dosage is right for you.

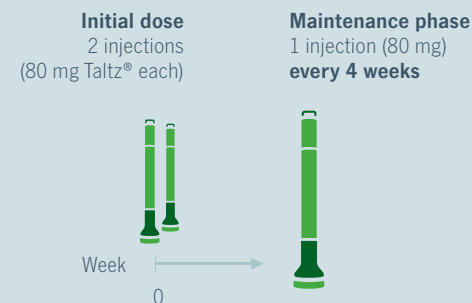
- You have psoriatic arthritis with mild psoriasis or no skin symptoms:

- You have psoriatic arthritis and moderate to severe psoriasis:

Use an appropriate **reminder method**, such as calendar entries, to help you remember your next dose so you do not miss it or take the same dose more than once.

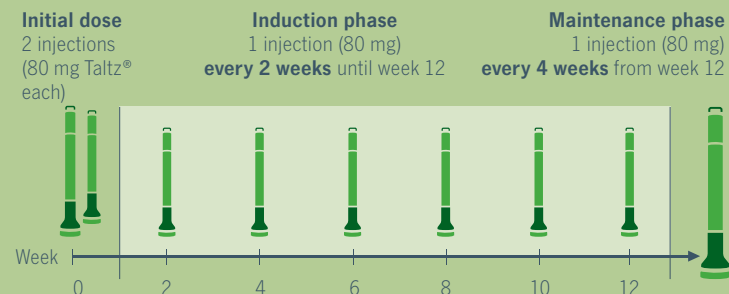
**Taltz® is intended for long-term treatment.** Your doctor or nurse will monitor your disease regularly to check that the treatment is having the desired effect.

- You have psoriatic arthritis with mild psoriasis or no skin symptoms:



- The first dose is 160 mg (two injections of 80 mg each).
- After the first dose, use one injection (80 mg) every four weeks.

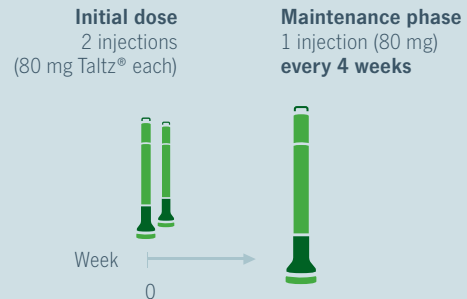
- You have psoriatic arthritis and moderate to severe psoriasis:



- The first dose is 160 mg (two injections of 80 mg each).
- After the first dose, you will use one injection (80 mg) every two weeks, i.e. in weeks 2, 4, 6, 8, 10 and 12 after starting therapy.
- From week 12, use one injection (80 mg) every 4 weeks.

## Dosage for axial spondyloarthritis

### You have axial spondyloarthritis:



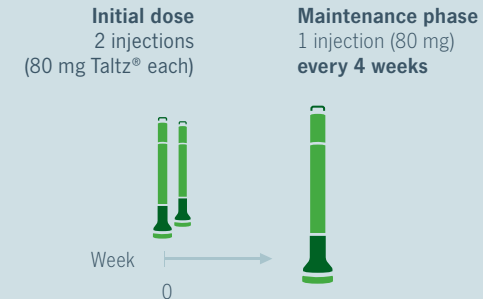
- The first dose is 160 mg (two injections of 80 mg each).
- After the first dose, use one injection (80 mg) every four weeks.

Use an appropriate **reminder method**, such as entries in a calendar or diary, to help you help you remember when your next dose is due so that you do not miss it or take the same dose more than once.

**Taltz® is intended for long-term treatment.** Your doctor or nurse will monitor your disease regularly to check that the treatment is having the desired effect.

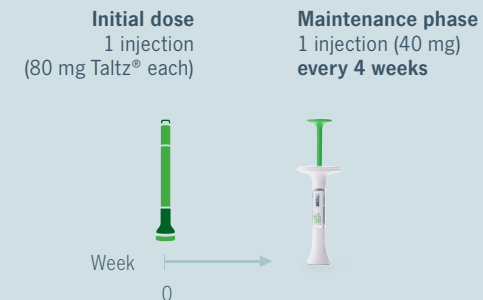
## Dosage for juvenile psoriatic arthritis and enthesitis-associated arthritis

### Your child weighs more than 50 kg:



- The first dose is 160 mg (two injections of 80 mg each).
- After the first dose, use one injection (80 mg) every four weeks.

### Your child weighs between 25 and 50 kg:



- The first dose is 80 mg (one injection of 80 mg).
- After the first dose, use one injection (40 mg) every four weeks.

Use an appropriate **reminder method**, such as entries in a calendar or diary, to help you help you remember when your next dose is due so that you do not miss it or take the same dose more than once.

**Taltz® is intended for long-term treatment.** Your doctor or nurse will monitor your disease regularly to check that the treatment is having the desired effect.

## Side effects

### What side effects can occur during treatment with Taltz®?

As with all medications, treatment with Taltz® can cause side effects, although these do not necessarily occur in every patient. The most common side effects include injection site reactions and upper respiratory tract infections.

Reactions at the injection site may also occur several days after the injection. These can be, for example, pain, redness or swelling. If you experience pain at the injection site and find it very uncomfortable, talk to your doctor.

Upper respiratory tract infections can cause symptoms such as sore throat and stuffy nose. Infections may generally be more severe during treatment with Taltz®. Therefore, go to the doctor as soon as you notice the first signs of a possible infection (e.g., nausea, flu-like infection, fungal infection).

Please also read the package leaflet for Taltz®.

### What should I do if I notice side effects?

If you notice any side effects, please tell your doctor so that he or she can advise you. This also applies to side effects that are not listed in the package leaflet.

## What should I do if I suspect I have a (serious) infection?

Taltz® may aggravate an existing infection or increase the chance that you will get a new infection. Tell your doctor if you notice symptoms of infection, such as:

- fever, flu-like symptoms, night sweats
- feeling tired or short of breath, persistent cough
- warm, red and painful skin or painful skin rash with blisters



## Special situations

### Can I get vaccinated during treatment with Taltz®? What about operations?

If you need a vaccination or are planning an operation, please talk to your doctor.

### I want to become pregnant or am pregnant, can I still use Taltz®?

The use of Taltz® during pregnancy should be avoided. Please inform your doctor immediately if you suspect you are pregnant or if you are confirmed to be pregnant. Consult your doctors if you want to become pregnant. Use a reliable method of contraception during Taltz® treatment and for at least 10 weeks after treatment has ended. Please consult your gynaecologist about this.

Discuss any questions you may have about breastfeeding with your doctor, as you must decide whether you would rather breastfeed or use Taltz®. You should not do both at the same time.

## What do I need to consider when planning a trip?

### Place Taltz® in the refrigerator at your destination

In general, Taltz® should be stored refrigerated. When you travel, you can take Taltz® with you without refrigeration. Please note that this is only possible for a limited period of time. Taltz® can be stored unrefrigerated for up to 5 days at a maximum temperature of 30°C. It is best to check in advance whether there is a cooling option on site.

### Take customs notice with you

To ensure that you can take Taltz® with you to other countries without any problems, you may need information for customs. You can download the customs information from our website [www.taltz.de](http://www.taltz.de).

### Pack Taltz® in your hand luggage

When travelling by plane, you should take your medication with you in your hand luggage. Make sure you have enough pens/syringes with you so that you can continue the recommended use even when travelling. Please also plan a reserve in case your return journey is delayed.

### Think about special vaccinations

Depending on the country you are travelling to, you may need to consider special vaccinations. In this case, please inform your doctor and discuss with him whether and how such vaccinations can be carried out during treatment with Taltz®.

## Tips and support

### What else can I do to positively influence the course of my illness?

To permanently relieve your symptoms, it is crucial that you take your medication regularly. In the case of axial spondyloarthritis, you should also undertake exercise therapy.

### You may also find it helpful to follow the following recommendations:

- Stay active: A walk every now and then and a healthy, balanced diet generally promote health and well-being.
- Relaxation does you good: Autogenic training or meditation can help you cope better with everyday stress.
- Fresh air instead of cigarettes: Try to reduce smoking, because smoking can worsen the symptoms.
- Talking can help: There are numerous patient organizations where you can meet like-minded people and get helpful information.

### Do you have any further questions that are not answered in this brochure?

Then please read the package leaflet for Taltz® or contact your treating specialist.

If you have general medical questions related to our products or if you need:

- Alcohol swabs and
- Puncture-proof container for disposal of pens and syringes

You can reach our Medical Information service from Monday to Friday by calling 06172 273 2222. **We are happy to be there for you.**

Your treating physician



Taltz® package leaflet, latest version.

A service provided by:  
Lilly Deutschland GmbH  
Werner-Reimers-Str. 2-4  
61352 Bad Homburg

*Lilly*  
A MEDICINE COMPANY

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