

# TALTZ® (CITRATE-FREE FORMULATION)

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

## 1. Why am I using TALTZ?

TALTZ contains the active ingredient ixekizumab. TALTZ is used to treat plaque psoriasis, psoriatic arthritis, ankylosing spondylitis (also known as radiographic axial spondyloarthritis) and non-radiographic axial spondyloarthritis.

For more information, see Section [1. Why am I using TALTZ?](#) in the full CMI.

## 2. What should I know before I use TALTZ?

Do not use if you have ever had an allergic reaction to TALTZ or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use TALTZ?](#) in the full CMI.

## 3. What if I am taking other medicines?

Some medicines may interfere with TALTZ and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

## 4. How do I use TALTZ?

- TALTZ is given as an injection under your skin, known as a subcutaneous injection. Your first dose will be given by a doctor, nurse or pharmacist.
- Each autoinjector or syringe contains one dose of TALTZ (80mg). The first dose of TALTZ for plaque psoriasis and psoriatic arthritis is 160 mg (two 80mg injections). The dose of TALTZ for radiographic and

non-radiographic axial spondyloarthritis is 80 mg (one injection).

More instructions can be found in Section [4. How do I use TALTZ?](#) in the full CMI.

## 5. What should I know while using TALTZ?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using TALTZ.</li><li>• Keep all of your doctor's appointments so that your progress can be checked.</li><li>• If you need to get vaccinated, tell your doctor you are taking TALTZ before you have the vaccination.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using TALTZ unless your doctor tells you to.</li><li>• Do not use TALTZ if you think it has been frozen or exposed to excessive heat.</li><li>• Do not use TALTZ if you notice that the</li></ul>

	autoinjector or syringe is damaged, or the medicine is cloudy, distinctly brown or has particles in it.
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• TALTZ autoinjector or syringe is single use only.</li> <li>• Keep your unused TALTZ autoinjector or syringe in a fridge between 2°C to 8°C. Do not freeze or shake.</li> <li>• Keep TALTZ in the original package in order to protect it from light.</li> </ul>

For more information, see Section [5. What should I know while using TALTZ?](#) in the full CMI.

## 6. Are there any side effects?

Side effects include injection site reactions (e.g. red skin or pain); stomach pain or diarrhoea due to inflammatory bowel disease; upper respiratory tract infections with symptoms such as sore throat and stuffy nose. More serious side effects include allergic reactions; severe itching of the skin, with red rash or raised bumps.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.





This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

## **TALTZ® (CITRATE-FREE FORMULATION)**

**Active ingredient:** *ixekizumab* (phonetic pronunciation - ixe-kiz-u-mab)

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### **Consumer Medicine Information (CMI)**

This leaflet provides important information about using TALTZ. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using TALTZ.**

### **Where to find information in this leaflet:**

1. Why am I using TALTZ?
2. What should I know before I use TALTZ?
3. What if I am taking other medicines?
4. How do I use TALTZ?
5. What should I know while using TALTZ?
6. Are there any side effects?
7. Product details

## 1. Why am I using TALTZ?

**TALTZ contains the active ingredient ixekizumab.**

Ixekizumab is a monoclonal antibody. Monoclonal antibodies are proteins that recognise and bind specifically to certain proteins in the body.

TALTZ belongs to a group of medicines called interleukin (IL) inhibitors. TALTZ works by neutralising the activity of the protein called IL-17A, which is present in high levels in psoriasis.

**TALTZ is used to treat:**

- **plaque psoriasis**
- **psoriatic arthritis**
- **ankylosing spondylitis (also known as radiographic axial spondyloarthritis)**
- **non-radiographic axial spondyloarthritis.**

**Plaque psoriasis** is a skin condition caused by inflammation affecting the skin. TALTZ reduces inflammation and other symptoms of the disease, such as scaling, itching and pain. TALTZ is used in adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

**Psoriatic arthritis** is an inflammatory disease of the joints, often accompanied by psoriasis. You will first be given other medicines to treat psoriatic arthritis but may be given TALTZ if you do not respond well to these medicines. TALTZ can be used alone or with other medicines, such as methotrexate.

## **Axial spondyloarthritis**

- **Ankylosing spondyloarthritis (radiographic axial spondyloarthritis)** is an inflammatory disease primarily affecting the spine which causes inflammation of the sacroiliac and spinal joints. This condition is visible with X-rays.
- **Non-radiographic axial spondyloarthritis** is an inflammatory disease primarily affecting the spine which causes inflammation of the sacroiliac and spinal joints. This condition is not visible with X-rays.

## **2. What should I know before I use TALTZ?**

### **Warnings**

#### **Do not use TALTZ if:**

- you are allergic to ixekizumab, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine
- if the product appears cloudy, discoloured, or contains particles
- if the packaging is torn or shows signs of tampering.

#### **Check with your doctor if you:**

- currently have an infection or have long-term or repeated infections

- have tuberculosis. You may be tested for tuberculosis before you receive treatment with TALTZ
- have ulcerative colitis or Crohn's disease
- are receiving any other treatment for psoriasis, such as immunosuppressants or phototherapy with ultraviolet (UV) light
- have recently had a vaccination or if you are due to have a vaccination during treatment with TALTZ
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## Vaccination

- Tell your doctor about your vaccination history.
- Live vaccines cannot be used while you are on TALTZ. You should consider completing all the immunisation required for your age group before starting on TALTZ.

## Pregnancy and breastfeeding

- Check with your doctor if you are pregnant or intend to become pregnant. The effects of TALTZ in pregnant women are not known.
- Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known if TALTZ is excreted in breastmilk.

## **Use in children**

TALTZ has not been studied in patients under 18 years of age.

## **Use in elderly**

TALTZ may be used in elderly patients aged 65 years and over.

This medicine is not addictive.

### **3. What if I am taking other medicines?**

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Tell your doctor, nurse or pharmacist if you have recently had or are due to have a vaccination. You should not be given certain types of vaccines while using TALTZ.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect TALTZ.**

### **4. How do I use TALTZ?**

TALTZ is given as an injection under your skin, known as subcutaneous injection.

## **You and your doctor, nurse or pharmacist should decide if you should inject TALTZ yourself.**

Your first dose will be given by a doctor, nurse or pharmacist. It is important not to try to inject yourself until you have been trained by a doctor, nurse or pharmacist. A caregiver may also give you your TALTZ injection after proper training.

## **How much to use**

Each autoinjector or syringe contains one dose of TALTZ (80 mg).

- Plaque psoriasis:**

- the first dose of TALTZ for plaque psoriasis is 160 mg (two 80 mg injections), followed by 80 mg (one injection) at weeks 2, 4, 6, 8, 10 and 12
- after 12 weeks, your treatment will continue at 80 mg (one injection) every 4 weeks.

- Psoriatic arthritis:**

- the first dose of TALTZ for psoriatic arthritis is 160 mg (two 80 mg injections), followed by 80 mg (one injection) every 4 weeks
- if you have psoriatic arthritis with moderate to severe psoriasis, your first dose of TALTZ is 160 mg (two 80 mg injections), followed by 80 mg (one injection) at weeks 2, 4, 6, 8, 10 and 12
- after 12 weeks, your treatment will continue as 80 mg (one injection) every 4 weeks.

- Axial spondyloarthritis (radiographic and non-radiographic):**

- the dose of TALTZ for axial spondyloarthritis is 80 mg (one injection) every 4 weeks.

You should inject the whole contents of the single use autoinjector or syringe.

## **When to use TALTZ**

TALTZ is for long-term treatment. Your doctor, nurse or pharmacist will regularly monitor your condition to check that the treatment is having the desired effect.

**Do not stop TALTZ just because you feel better. It is important that you do not stop using TALTZ unless your doctor tells you.**

It is not dangerous to stop using TALTZ. However, if you stop, your psoriasis symptoms may come back.

## **How to use TALTZ**

Read the instructions for use for the autoinjector or syringe carefully before using TALTZ.

## **If you forget to use TALTZ**

If you have forgotten to inject a dose of TALTZ, inject the dose as soon as you remember, then talk to your doctor to discuss when you should inject the next dose.

## **If you use too much TALTZ**

If you think that you have used too much TALTZ, or injected sooner than according to your doctor's prescription, you may need urgent medical attention.

## **You should immediately:**

- phone the Poisons Information Centre  
**(by calling 13 11 26)**, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while using TALTZ?**

### **Things you should do**

- Keep all of your doctor's appointments so that your progress can be checked.
- Your doctor will do tests from time to time to make sure TALTZ is working and to prevent unwanted side effects.
- If you need to get vaccinated, tell your doctor you are taking TALTZ before you have the vaccination. You should not be given a live vaccination while being treated with TALTZ.
- Remind any doctor, dentist or pharmacist you visit that you are using TALTZ.
- While you are using TALTZ, tell your doctor or pharmacist before you start any new medicine.
- Tell your doctor if you become pregnant or plan to breastfeed while using TALTZ.

## Things you should not do

- Do not use the medicine if you think it has been frozen or exposed to excessive heat. It may not work as well.
- Do not use the medicine if you notice that the autoinjector or syringe is damaged, or the medicine is cloudy, distinctly brown or has particles in it.
- Do not give your TALTZ to anyone else, even if they have the same condition as you. Your doctor has prescribed TALTZ specifically for you.

## Looking after your medicine

- A TALTZ autoinjector or syringe is for single use only.
- Keep your unused TALTZ autoinjector or syringe in a fridge between 2°C to 8°C. Do not freeze or shake.
- Do not use if it has been frozen.
- Keep TALTZ in the original package in order to protect it from light.
- If needed, the TALTZ autoinjector or syringe can be left out of the refrigerator for up to 5 days at a temperature not above 30°C, for example while travelling or transporting it from the pharmacy.

Follow the instructions in the carton on how to take care of your medicine properly.

**Keep TALTZ where young children cannot reach it.**

## **When to discard your medicine**

After 5 days out of the refrigerator, the TALTZ autoinjector or syringe must be discarded.

## **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

- Empty autoinjectors and syringes should be disposed of in a sharps container or similar puncture proof container composed of hard plastic or glass.
- Ask your doctor, nurse or pharmacist where you can dispose of the container once it is full.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

## Less serious side effects

Less serious side effects	What to do
<p><b>Injection site reactions:</b></p> <ul style="list-style-type: none"><li>• red skin or pain</li></ul> <p><b>Infection:</b></p> <ul style="list-style-type: none"><li>• upper respiratory tract infections with symptoms such as sore throat and stuffy nose</li><li>• fever, sore throat or mouth ulcers</li><li>• running nose</li><li>• influenza</li></ul> <p><b>Fungal infection:</b></p> <ul style="list-style-type: none"><li>• athlete's foot</li><li>• oral thrush</li></ul> <p><b>Oropharyngeal related:</b></p> <ul style="list-style-type: none"><li>• pain in the back of the throat</li></ul> <p><b>Eye related:</b></p> <ul style="list-style-type: none"><li>• discharge from the eye with itching, redness and swelling</li></ul> <p><b>Gastrointestinal:</b></p> <ul style="list-style-type: none"><li>• nausea (feeling sick)</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● stomach pain or diarrhoea due to inflammatory bowel disease (including ulcerative colitis or Crohn's disease)*</li> </ul> <p><b>Skin related:</b></p> <ul style="list-style-type: none"> <li>● itchy rash, dry skin, dry patches, inflamed skin, coin-shaped spots on the skin (dermatitis (including eczema))</li> <li>● blisters on the sole of the feet or the palms of the hands and fingers (dyshidrotic eczema)</li> </ul>	

\*New cases of inflammatory bowel disease or "flare-ups" can happen with TALTZ and can sometimes be serious. If you have inflammatory bowel disease (ulcerative colitis or Crohn's disease), tell your doctor if you have worsening symptoms during treatment, or develop new symptoms such as stomach pain or diarrhoea.

## Serious side effects

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Skin related:</b></p> <ul style="list-style-type: none"><li>• Severe skin peeling and inflammation of most of the skin surface (exfoliative dermatitis)</li></ul> <p><b>Signs of serious allergic reaction - signs may include:</b></p> <ul style="list-style-type: none"><li>• difficulty in breathing or swallowing</li><li>• swelling of the face, lips, tongue or throat</li><li>• severe itching of the skin, with red rash or raised bumps, hives</li></ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>
<p><b>Possible serious infections - signs may include:</b></p> <ul style="list-style-type: none"><li>• fever, flu-like symptoms, night sweats</li><li>• feeling tired or short of breath, cough which will not go away</li></ul>	<p><b>Stop using TALTZ and call your doctor immediately. Your doctor will decide if and when you may restart treatment</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"><li>• warm, red and painful skin or painful skin rash with blisters</li></ul>	

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## **7. Product details**

This medicine is only available with a doctor's prescription.

## **What TALTZ contains**

<b>Active ingredient</b>	Ixekizumab (rch)
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<b>(main ingredient)</b>	
<b>Other ingredients (inactive ingredients)</b>	<p>Sucrose</p> <p>Polysorbate 80</p> <p>Water for injections</p> <p>Sodium hydroxide may be added to adjust pH</p>

**Do not take this medicine if you are allergic to any of these ingredients.**

## **What TALTZ looks like**

TALTZ is a clear solution for injection. Its colour may vary from colourless to slightly yellow.

TALTZ may be available as a prefilled autoinjector (also known as a pen) (AUST R 414414) or a prefilled syringe (AUST R 414413), in pack sizes of 1 or 2.

Not all presentations or pack sizes may be available.

## **Who distributes TALTZ**

Eli Lilly Australia Pty Ltd

Level 9, 60 Margaret Street

Sydney NSW 2000

[www.lilly.com.au](http://www.lilly.com.au)

Phone: 1800 454 559

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