▼**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.**

TALTZ®

Prefilled Autoinjector and Prefilled Syringe
Ixekizumab (rch) (pronounced ixe-kiz-u-mab)

Consumer Medicine Information

What is in this leaflet

This leaflet is designed to provide you with answers to some common questions about this medicine.

All medicines have risks and benefits. Your doctor has more information about this medicine than is contained in this leaflet.

If you have any concerns about using this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.
You may need to read it again.

What TALTZ is used for

TALTZ is used to treat:

- plaque psoriasis
- psoriatic arthritis
- ankylosing spondylitis (also known as 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.

Ankylosing spondylitis is an inflammatory disease primarily affecting the spine which causes inflammation of the sacroiliac and spinal joints.

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

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

TALTZ is available only with a doctor's prescription.

TALTZ is not addictive.

Ask your doctor, nurse or pharmacist if you have any questions about why this medicine has been prescribed for you.

Before you use TALTZ

Tell your doctor if you have any of the following conditions or if you have ever experienced any of these conditions.

When you must not use TALTZ

Do not use TALTZ:

- **if you are allergic to ixekizumab or to any of the ingredients listed at the end of this leaflet (see 'Product Description').**
  Some of the symptoms of an allergic reaction may include:
  - chest tightness, wheezing or difficulty breathing
  - severe dizziness or lightheadedness
  - swelling of the face, lips, tongue, throat or other parts of the body
  - rash, itching or hives on the skin
  If you think you are allergic, ask your doctor for advice before using TALTZ.
- **if the product appears cloudy, discoloured or contains particles**
- **if the packaging is torn or shows signs of tampering**
- **if the expiry date (EXP) on the pack has passed.**
  If the medicine has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using TALTZ, talk to your doctor, nurse or pharmacist.

Before you start to use TALTZ

You must tell your doctor before using TALTZ:

- if you currently have an infection or if you have long-term or repeated infections
- if you have tuberculosis
- if you have ulcerative colitis or Crohn's disease
- if you have recently had a vaccination or if you are due to have a vaccination during treatment with TALTZ
- if you are receiving any other treatments for psoriasis, such as immunosuppressant or phototherapy with ultraviolet (UV) light.

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.

You may be tested for tuberculosis before you receive treatment with TALTZ.

Tell your doctor if you are pregnant, you think you may be pregnant or intend to become pregnant.
The effects of TALTZ in pregnant women are not known. Talk to your doctor about the benefits to you using TALTZ versus the potential risk to your unborn child.

Tell your doctor if you are breast-feeding or plan to breast-feed.
It is not known if TALTZ is excreted in breast milk. Talk to your doctor about breast-feeding before taking TALTZ.

Tell your doctor about these things before you use TALTZ.

Taking other medicines

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

Tell your doctor, nurse or pharmacist if you:

- are using, have recently used or might use any other medicine.
- have recently had or are due to have a vaccination. You should not be given certain types of vaccines while using TALTZ.

How to use TALTZ

Follow all directions given to you by your doctor, nurse or pharmacist carefully.
These may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor, nurse or pharmacist for help.

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

TALTZ is given as an injection under your skin, known as a 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

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 as 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.

Ankylosing spondylitis
The dose of TALTZ for ankylosing spondylitis is 80 mg (one injection) every 4 weeks.

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

How to use it

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

How long do I use it

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.

If you miss a dose

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

If you have any further questions on the use of this medicine, ask your doctor, nurse or pharmacist.

If you use more than you should (overdose)

If you accidentally injected more TALTZ than you should or sooner than according to your doctor's prescription, immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26 for Australia) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much TALTZ.

Do this even if there are no obvious signs of discomfort or poisoning.

While you are using TALTZ

Things you must 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 be 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.

Tell all doctors, dentists and pharmacists who are treating you 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 must 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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using TALTZ.

Like all medicines, TALTZ may cause some unwanted side effects, although not everybody gets them.

Tell your doctor as soon as possible about any unwanted side effects.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor immediately or go to Emergency at your nearest hospital if you notice any of the following:

- Signs of serious allergic reactions such as difficulty in breathing or swallowing
- Swelling of the face, lips, tongue or throat
- Severe itching of the skin, with red rash or raised bumps.

Stop using TALTZ and tell your doctor immediately if you get any of the following side effects. Your doctor will decide if and when you may restart treatment.

- Possible serious infections - 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 painful skin rash with blisters.

Tell your doctor if you experience any of the following side effects:

- upper respiratory tract infections with symptoms such as sore throat and stuffy nose
- injection site reactions (e.g. red skin or pain)
- nausea (feeling sick)
- athlete's foot (tinea)
- pain in the back of the throat
- fever, sore throat or mouth ulcers due to infections.
- stomach pain or diarrhoea due to inflammatory bowel disease (including ulcerative colitis or Crohn's disease).

The above list includes more of the common side effects. They are usually mild to moderate and short-lived.

Other uncommon side effects include:

- oral thrush
- influenza
- runny nose
- hives
- discharge from the eye with itching, redness and swelling.

Do not be alarmed by this list of side effects.
You may not experience any of them.

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 with TALTZ or develop new symptoms of stomach pain or diarrhoea.

Tell your doctor if you notice anything unusual or if you are concerned about any aspect of your health, even if you think the problems are not connected with this medicine and are not referred to in this leaflet.

Other side effects not listed above may also occur in some people.

After using TALTZ

Storage

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

Do not use an autoinjector or syringe after the expiry date which is stamped on the label and outer carton after "EXP" (month/year).
The expiry date refers to the last day of that month.

All medicines should be kept out of sight and reach of children.

Disposal

If your doctor tells you to stop using TALTZ or you find your autoinjector or syringe has passed their expiry date, please return it to your pharmacist.

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.

You can also refer to the autoinjector or syringe 'Instructions for Use' for additional information on storage and handling of this medicine.

Product description

What it looks like

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

TALTZ is available as an autoinjector (also known as a pen) and a prefilled syringe in pack sizes of 1 or 2.

Not all pack sizes may be available.

Ingredients

Active Ingredient:

- ixekizumab (rch) (80 mg)

Inactive Ingredients:

- sodium citrate dihydrate
- citric acid
- sodium chloride
- polysorbate 80
- water for injections

Supplier

Supplied in Australia by:

Eli Lilly Australia Pty Limited
112 Wharf Road
WEST RYDE, NSW 2114
www.lilly.com.au

Australian Registration Numbers:

TALTZ prefilled autoinjector
AUST R 253893

TALTZ prefilled syringe
AUST R 253892

If you have any questions about TALTZ, contact Eli Lilly at 1800 454 559 (Australia) or your healthcare professional for assistance.

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