

PATIENT INFORMATION ON IXEKIZUMAB

(Brand names: Taltz)

This information sheet has been produced by the Australian Rheumatology Association to help you understand the medicine that has been prescribed for you. It includes important information about: how you should take your medicine

- **what are the possible side effects**
- **what tests you must have to monitor your condition and to detect unwanted effects**
- **other precautions you should take when you are taking ixekizumab**

Please read it carefully and discuss it with your doctor.

Important things to remember

- While having treatment with ixekizumab you must see your rheumatologist regularly to ensure the treatment is working and minimise any possible side effects.
- If you stop ixekizumab for any reason you must contact your doctor.
- Remember to change the injection site each time ixekizumab is injected.
- If you are worried about any side effects you should contact your rheumatologist as soon as possible.
- If you need a vaccination, tell your doctor you are being treated with ixekizumab before you have the vaccination. Some vaccines cannot be given while on ixekizumab.
- If you are having treatment with ixekizumab and plan to become pregnant you must discuss the timing with your doctor.

For more information about PSORIATIC ARTHRITIS and other inflammatory conditions see Arthritis Australia's website:
www.arthritisaustralia.com.au

What is ixekizumab?

- Ixekizumab (brand name: Taltz®) is a medicine used to treat adults with psoriatic arthritis, an inflammatory disease of the joints that is often accompanied by psoriasis. Ixekizumab is also used to treat adults with moderate to severe plaque psoriasis that is chronic (lasts for a long time).
- Ixekizumab is a monoclonal antibody which is a protein that recognises and binds to an inflammatory protein called Interleukin 17A (IL-17A). In patients with psoriatic arthritis, the body's immune system produces an increased amount of IL-17A which causes the symptoms such as swollen and painful joints. Ixekizumab blocks the action of IL-17A in the body, reducing the inflammation and other symptoms caused by the increased amount of IL-17A.

What benefit can you expect from your treatment?

Ixekizumab is a medicine to treat active psoriasis and psoriatic arthritis. It may take a number of weeks for you to notice relief of joint pain, swelling and stiffness.

How is ixekizumab taken?

Ixekizumab is injected just under the skin (subcutaneously) of the thigh or abdomen. It is best to avoid (if possible) any areas of skin involved with psoriasis. The prefilled autoinjector or syringe should be taken out of refrigerator 20 minutes before injecting to allow it to reach room temperature. Do not shake or freeze it. It can be injected by your doctor, nurse, carer, or by you. If injecting yourself, be sure to follow the detailed instructions carefully to ensure the best response. It is important to change the injection site each time.

If you forget to use it

If you forget an injection, make the next injection as soon as you remember and continue to use it as you normally would. Do not inject a double dose to make up for the one you missed. If you have missed more than one dose or are not sure what to do, check with your doctor or pharmacist.

If you have used too much (overdose)

Let your doctor know as soon as possible if you accidentally use more than your prescribed dose. The risk of adverse events is higher with larger doses.

What is the dosage?

Ixekizumab is an 80mg prefilled syringe or prefilled autoinjector. The usual starting dose is 2 injections, followed by 1 injection every 4 weeks.

Can other medicines be taken with ixekizumab?

Ixekizumab may be taken in combination with other arthritis medicines, including:

- steroid medicines such as prednisolone or cortisone injections into the joint
- anti-inflammatory medicines (NSAIDs) such as naproxen (Naprosyn) or ibuprofen (Brufen/Nurofen)
- simple pain-relieving medicines such as paracetamol
- methotrexate

There are separate information sheets for the medicines mentioned above.

How long is the treatment continued?

Treatment can continue with ixekizumab as long as it is effective and you are not experiencing any adverse effects. Your doctor will tell you how long to continue treatment with ixekizumab.

Are there any side effects?

As with most medicines, ixekizumab may cause side effects in some people. You may need medical treatment if you get some side effects. Tell your doctor if you are concerned about any possible side effects.

Most common possible side effects

- The most common side effects with ixekizumab are upper respiratory infections such as stuffy nose and sore throat. These are usually mild. Tell your doctor if you are concerned, or if the side effects persist for a long time.
- Other common side effects include cold sores, diarrhoea, hives, headache, nausea or itchy rash (urticaria).

Less common or rare possible side effects

Other less common side effects include oral thrush, signs of low white cells (such as fever, sore throat or mouth ulcers due to infections), athlete's foot, ear infections, painful periods, conjunctivitis or discharge from the eye with itching, redness and swelling.

There are some rare but potentially serious side effects with ixekizumab:

- Serious allergic reaction: Signs of a serious allergic reaction may include a skin rash, a swollen face, lips, mouth or throat, or wheezing, dizziness, trouble swallowing or breathing. Tell your doctor or go to the hospital immediately if you have an allergic reaction as you need urgent medical attention.

- Inflammatory bowel disease: New cases of inflammatory bowel disease or "flare ups" after periods of remission can occur while being treated with ixekizumab. If you have inflammatory bowel disease, tell your doctor if you have worsening symptoms during treatment with ixekizumab, or if you develop new symptoms of stomach pain or diarrhoea.

Other side effects not listed in this leaflet may also occur. Tell your doctor if you notice any other side effects that you think might be caused by ixekizumab.

What precautions are necessary?

Before treatment is started with ixekizumab, your doctor will examine you for tuberculosis (TB). If your doctor feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment and during treatment with ixekizumab.

Use with other medicines

- Ixekizumab may interact with some other medicines. You should tell your doctor (including your general practitioner, rheumatologist and others) about all medicines you are taking or plan to take. This includes over the counter or herbal/naturopathic medicines. You should also mention your treatment when you see other health professionals.
- While being treated with ixekizumab, you must not receive live vaccines. Tell your doctor if anyone in your house needs a vaccine. The viruses in some vaccines can spread to people with a weakened immune system and can cause serious problems.

Use in pregnancy and when breastfeeding

- The effects of ixekizumab during pregnancy have not been well studied, so it is not clear if it causes birth defects. Treatment of pregnant women with ixekizumab may affect the immunity of their baby. Women of childbearing potential should use effective methods of contraception during treatment and for at least 10 weeks after treatment.
- If you are pregnant or are considering having a child you should discuss this with your doctor before beginning this medication.
- If you have been treated with ixekizumab during your pregnancy, you should check with your doctor before vaccinations are given to your baby. Some vaccines cannot be given to the newborn baby if you were treated with ixekizumab while you were pregnant.
- It is not known whether ixekizumab is excreted in the breastmilk of lactating women. Women who are breastfeeding should talk to their doctor about whether or not to use ixekizumab.

How to store ixekizumab

- Store ixekizumab in the refrigerator, between 2 and 8 degrees Celsius. Do not freeze. If necessary ixekizumab may be stored unrefrigerated for a single period of up to 5 days at room temperature, not above 30 degrees Celsius. Keep the syringe in the original carton to protect them from light until the time of use.

- Keep all medicines out of reach of children.
 - Do not leave ixekizumab in the car, on windowsills or in the bathroom. Heat can destroy some medicines, including ixekizumab.

Disposal

- After injecting ixekizumab, the used syringes should be placed in a puncture resistant container, like a sharps container. Dispose of your sharps

container according to your state or local regulations. If unsure how to dispose of your sharps container, ask your pharmacist.

- If your doctor tells you to stop using ixekizumab, or the expiry date has passed, ask your pharmacist what to do with the leftover medicine.

<p>Questions?</p> <p>If you have any questions or concerns write them down and discuss them with your doctor.</p> <p>Your doctor's contact details</p> <p>You should see your rheumatologist regularly to make sure the treatment is working and to minimise any potential side effects.</p>	<p>How to help us help you Sign up to the ARAD project now!</p> <p>The Australian Rheumatology Association collects information on how well these drugs work and how often they cause problems.</p> <p>The best way to get this information is from you! Contact us in any of the following ways:</p> <p>Email: ARAD@monash.edu Telephone: 03 9508 3424</p> <p>Visit our website: www.ARAD.org.au</p>
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The information in this sheet has been obtained from various sources and has been reviewed by the Australian Rheumatology Association. It is intended as an educational aid and does not cover all possible uses, actions, precautions, side effects, or interactions of the medicines mentioned. This information is not intended as medical advice for individual problems nor for making an individual assessment of the risks and benefits of taking a particular medicine. It can be reproduced in its entirety but cannot be altered without permission from the ARA. The NHMRC publication: *How to present the evidence for consumers: preparation of consumer publications* (2000) was used as a guide in developing this publication.