

PATIENT INFORMATION ON IXEKIZUMAB

[ix-e-KIZ-you-mab]

(Brand name: 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**
- **the possible side effects**
- **what tests you will have to watch your condition**
- **other precautions you should take.**

Please read it carefully and discuss it with your rheumatologist.

IMPORTANT THINGS TO REMEMBER

- You must see your rheumatologist regularly to make sure the treatment is working and check for possible side effects.
- You should have regular blood tests as suggested by your rheumatologist.
- It is important to tell your rheumatologist if you have a new serious illness such as a serious infection, cancer, heart failure etc.
- 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 stop ixekizumab for any reason, you must contact your rheumatologist. Failure to do so may mean that your treatment may no longer be funded.
- If you plan to become pregnant, you must discuss the timing with your rheumatologist.

For more information about PSORIATIC ARTHRITIS and other inflammatory conditions associated with arthritis, 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 may also be used to treat adults with axial spondyloarthritis, including ankylosing spondylitis, an inflammatory disease which primarily affects the spine, causing inflammation and pain in the spinal joints.

Ixekizumab is a monoclonal antibody which is a protein that recognises and binds to an inflammatory protein called Interleukin 17A (IL17A). 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?

You may notice reduced joint swelling, pain and stiffness, often within the first 8 weeks of starting.

Stopping ixekizumab

If you stop or delay your ixekizumab treatment, your condition may get worse. Keep on your treatment, unless told by your rheumatologist to stop or unless side effects occur (see Side effects).

If you stop ixekizumab for any reason, you must contact your rheumatologist. Failure to do so may mean that your treatment may no longer be funded.

How will you be checked while on ixekizumab?

Medicines like ixekizumab are very expensive and funded by Medicare. Certain conditions must be met to receive it.

- Ixekizumab will only be given if your disease is active and if standard treatments have not worked.
- It will only be kept going if it helps your condition. This must be checked between 12 and 16 weeks after the start of treatment.
- Blood tests are needed during your treatment to watch for side effects and decide if the treatment is working.



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- How often you have blood tests will depend on what other medicines you are taking and what other illnesses you might have. Your rheumatologist will advise on this.

How is ixekizumab given?

Ixekizumab is injected just under the skin 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 the refrigerator 30 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 miss an injection: administer 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 a missed dose. If you have missed more than one dose or are not sure what to do, check with your doctor or pharmacist.

What is the dosage?

Ixekizumab is an 80mg prefilled syringe or prefilled autoinjector. The usual starting dose is:

- For psoriatic arthritis - 2 injections, followed by 1 injection every 4 weeks.
- For axial spondyloarthritis or non-radiographic axial spondyloarthritis – 1 injection every 4 weeks.

Can other arthritis medicines be taken with ixekizumab?

This medicine may be used alone or with other arthritis medicines including:

- Other Disease Modifying Anti Rheumatic Drugs (DMARDs) such as methotrexate.
- 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 medicines such as paracetamol.

Are there any side effects?

You might experience side effects with your treatment. Tell your doctor if you notice side effects that you think are caused by this medicine. Many side effects disappear when ixekizumab treatment is stopped.

Most common possible side effects

You may experience more frequent mild upper respiratory tract infections (common cold, sinus infections), nausea, diarrhoea, cough, and fever. Infections may need treatment and ixekizumab may need to be stopped for a while if you develop infection, so it is important to contact your doctor for advice.

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, 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, 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? Infections

If you have an active infection of any kind, treatment with ixekizumab will not be started until the infection is treated successfully.

Serious infections such as tuberculosis (TB) are seen rarely, and screening for TB may be needed before treatment begins.

Use with other medicines

Ixekizumab can interact with other medicines. You should tell all your doctors about all medicines you are taking or plan to take. This includes over the counter or herbal/naturopathic medicines.

Use with phototherapy

Ixekizumab should not be used while receiving light therapy (PUVA) for psoriasis.

Vaccines

- While being treated with ixekizumab you should not be immunised with 'live' vaccines such as:
MMR (measles, mumps and rubella), Varicella vaccines (Chicken pox/Shingles), OPV (oral polio virus), BCG (Bacillus Calmette Guerin), Japanese Encephalitis or Yellow Fever. Talk with your rheumatologist before receiving any vaccines.
- Pneumococcal vaccines and the yearly seasonal flu vaccinations are encouraged.
- For more information on vaccination including the COVID-19 vaccination go to:
<https://rheumatology.org.au/For-Patients/Medication-Information/Vaccinations/Vaccinations-in-Rheumatology>

Surgery

If you require surgery for any reason, you should discuss this with your rheumatologist as some people need to stop taking ixekizumab before surgery.

Alcohol

You may drink alcohol while taking ixekizumab. However, if you are also taking methotrexate, you should be cautious about how much alcohol you drink.

Pregnancy, breastfeeding and fertility

- 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.
- There is no information on the effect of ixekizumab on fertility.
- 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.

- More detailed information is available at <https://rheumatology.org.au/For-Healthcare-Professionals/Clinical-Resources/Pregnancy-Prescribing-Info>

How to store ixekizumab

- Store ixekizumab in the refrigerator, between 2 and 8°C. 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°C. Keep the syringes in the original carton to protect them from light until the time of use.
- Keep all medicines out of reach of children.

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.

Questions?

If you have any questions or concerns write them down and discuss them with your doctor.

Your doctor's contact details

You should see your rheumatologist regularly to make sure the treatment is working and to minimise any possible side effects.

This Information Sheet has been prepared using materials obtained from various sources which have been reviewed by the Australian Rheumatology Association (ARA). It contains general information only and does not contain a complete or definitive statement of all possible uses, actions, precautions, side effects or interactions of the medicines referenced. This information is not intended as medical advice for individual conditions nor for making an individual assessment of the risks and benefits of taking a particular medicine. Decisions regarding the assessment and treatment of patients are the sole responsibility of the treating medical professional, exercising their own clinical judgment and taking into account all of the circumstances and the medical history of the individual patient.

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