

PATIENT INFORMATION ON USTEKINUMAB

(Brand name: Stelara)

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 may have to monitor your condition and to detect unwanted effects, and**
- **other precautions you should take.**

Please read it carefully and discuss it with your doctor.

Important things to remember

- While taking ustekinumab you must see your rheumatologist regularly to ensure the treatment is working and minimise any possible side effects.
- If you stop ustekinumab for any reason you must contact your doctor. Failure to do so may mean that your continued treatment will no longer be subsidised.
- Remember to change the injection site each time ustekinumab is injected.
- If you are worried about any side effects you should contact your rheumatologist as soon as possible.
- It is important to tell your doctor if you have had cancer or if you develop cancer.
- If you are taking ustekinumab and plan to become pregnant you must discuss the timing with your doctor.
- You should continue to take it even if you do not have symptoms.

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

What is ustekinumab?

Ustekinumab (brand name: Stelara®) is a medicine used to treat adults with psoriatic arthritis, an inflammatory disease of the joints that is often accompanied by psoriasis. Ustekinumab is also used to treat adults with moderate to severe plaque psoriasis, that is chronic (lasts for a long time).

Ustekinumab is a monoclonal antibody which is a protein that recognises and binds to other unique proteins. Ustekinumab blocks the action of two proteins in the body that are made by your body's immune system. By blocking the two proteins, ustekinumab may block the inflammatory pathways in psoriatic arthritis and psoriasis.

What benefit can you expect from your treatment?

Ustekinumab is a new medicine used for patients who have severe active psoriatic arthritis. It does not work straight away. It may take a number of weeks for you to notice some relief of joint swelling, pain and stiffness.

How is ustekinumab taken?

Ustekinumab is injected just under the skin (subcutaneously) of the abdomen or thigh. It is best to avoid (if possible) any areas of skin involved with psoriasis.

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 particularly important to change the injection site each time.

Do not shake the vials of ustekinumab at any time. Vigorous shaking may damage the product.

Vials that have been shaken vigorously should not be used.

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)

Contact your doctor straight away or go to your nearest hospital, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

What is the dosage?

Ustekinumab is a solution for injection that comes in a glass vial. Each vial contains 45mg of ustekinumab. The usual dose of ustekinumab is 45mg (the contents of one vial) injected when you start treatment, then again 4 weeks later, and every 12 weeks after that.

Can other arthritis medicines be taken with ustekinumab?

Ustekinumab 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.

There are separate information sheets for the medicines mentioned above.

How long is the treatment continued?

Treatment can continue with ustekinumab 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 ustekinumab. If you see no improvement in your symptoms after 28 weeks of ustekinumab treatment, the treatment will be stopped.

Are there any side effects?

As with most medicines, ustekinumab 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 ustekinumab are upper respiratory infections such as *sinus infection, sore throat* or *headache*. These are usually mild. Tell your doctor if you are concerned, or if the side effects persist for a long time.

Less common or rare possible side effects

Other less common side effects include *dental infections, injection site pain or redness, skin rash or itchiness, diarrhoea* or *nausea, tiredness* or *depression*.

There are some rare but potentially serious side effects with ustekinumab.

- 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.
- Serious infections: Ustekinumab may lower your ability to fight infections. Some infections could become serious and you may need to be admitted to hospital. If you have an infection before you start treatment with ustekinumab, you must tell your doctor. If you get an infection while on ustekinumab, tell your doctor straight away.
- Cancer: Some drugs like ustekinumab that decreases the activity of the immune system may increase the risk of cancer. Tell your doctor if you have ever had any type of cancer.

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 ustekinumab.

What precautions are necessary?

Before treatment is started with ustekinumab, 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 ustekinumab. Because ustekinumab can increase the risk of infection, you will be monitored for TB throughout the treatment.

Use with other medicines

- Ustekinumab can 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.
- Some medicines that ustekinumab may interfere with, include *warfarin*, and *cyclosporin*. Make sure your doctor is aware if you are taking these medicines.
- While being treated with ustekinumab, 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 ustekinumab during pregnancy have not been well studied, so it is not clear if it causes birth defects.
- If you are pregnant or are considering having a child you should discuss this with your doctor before beginning this medication.
- Ustekinumab is likely to be excreted in the breastmilk of lactating women. Women who

are breastfeeding should talk to their doctor about whether or not to use ustekinumab.

How to store ustekinumab

- Store ustekinumab in the refrigerator, between 2 degrees Celcius and 8 degrees Celcius. Do not freeze. Keep the vials in the original carton to protect them from light until the time of use. Do not shake the vials.
- Keep all medicines out of reach of children.
- Do not leave ustekinumab in the car, on windowsills or in the bathroom. Heat and dampness can destroy some medicines

Disposal

- After injecting ustekinumab, the used syringes should be placed in a punctureresistant 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.
- Empty vials, antiseptic wipes, and other supplies can be placed in the regular rubbish.
- If your doctor tells you to stop using ustekinumab, 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

If you are taking ustekinumab you should see your doctor regularly to make sure the treatment is working and to minimise any possible side effects.

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.