



USTEKINUMAB

What are the aims of this leaflet?

This leaflet has been written to help you understand more about ustekinumab (Stelara™). It tells you what it is, how it works, how it is used to treat skin conditions, and where you can find out more about it.

What is ustekinumab and how does it work?

Ustekinumab is a drug that has been specially designed to mimic normal human molecules, and for this reason it is classed as a 'biological' drug. It reduces skin inflammation by blocking the activity of chemical molecules called cytokines (interleukin 12 and 23) in the body that trigger inflammation in psoriasis.

Which conditions are treated with ustekinumab?

Ustekinumab is used to treat moderate to severe plaque psoriasis in patients of age 12 years and older.

Why have I been selected for treatment with ustekinumab?

Ustekinumab is only used for patients with severe psoriasis who cannot take standard treatments for psoriasis either because they do not work, cannot be tolerated or the treatment is not suitable. There are national guidelines that assist dermatologists in identifying those patients that might benefit from and are eligible for ustekinumab.

How long will I need to take ustekinumab before it has an effect?

Ustekinumab does not work immediately. It may be 3-12 weeks before any benefit is noticed. In clinical trials, about 67% of patients achieved a good

response (which means a 75% improvement in psoriasis lesions) after 3 months' treatment.

How do I take ustekinumab?

Ustekinumab is supplied as a sterile solution in a single-use pre-filled syringe containing 45 mg ustekinumab in 0.5 ml and should be injected under the skin of the stomach, thighs or upper outer arms. A nurse or doctor will demonstrate how to inject yourself and details are also given in the drug package insert. It must be stored in a refrigerator (at 2-8 °C) and the vial must remain within the cardboard box to protect it from the light. Travelling with ustekinumab or transporting your treatment requires a cool box or cool bag with icepacks to maintain these temperatures. You will be provided with sharps bins so that you can dispose of your syringes and needles safely.

What dose should I take?

The dose of ustekinumab for an adult patient with psoriasis weighing up to 100 kg is 45 mg (one injection) at week 0, one injection at week 4 and then an injection once every 12 weeks from then on. For patients weighing more than 100 kg, the dose is 90 mg (two injections) and is given at the same times as the lower dose (i.e. week 0, week 4, and then every 12 weeks from then on).

Your response to treatment after four months will be measured by your dermatologist. If there is a good response, the treatment will then normally be continued to maintain improvement with an injection once every 12 weeks.

In patients aged 12-18 years, the dose will depend on the body weight and your dermatologist will advise you on the dose required.

What are the possible side effects of ustekinumab?

Mild and common

- *Reactions at the injection sites.* These are usually mild and include [redness](#), a rash, swelling, itching, or bruising. They usually go away within 3 to 5 days. If you have pain, [redness](#) or swelling around the injection site that does not go away or gets worse, you should contact your doctor.
- *Upper respiratory infections*, for example, sinus infections. Try to avoid close contact with anyone with a bad cold or chest infections and wash your hands frequently when taking this medication.
- *Headaches, dizziness, rash, diarrhoea*

- *Fatigue*

Potentially severe

- *Serious infections.* Ustekinumab may decrease your ability to fight infection. Inform your doctor of any current or past infection (particularly tuberculosis), or if you are prone to infections such as cold sores or cystitis. Also tell your doctor if you have or have ever had any disease that affects your immune system, such as cancer, human immunodeficiency virus (HIV) infection or viral hepatitis. Avoid dairy foods that are not pasteurised. Camembert, Brie and blue cheeses, pâté or eggs, meat or poultry that are not adequately cooked pose a risk of salmonella infection. Contact your doctor if you get an infection, or any symptom or sign of an infection, including: a fever, lethargy, a cough, influenza-like symptoms, warm, red or painful skin, swollen glands or open sores on your body.
- *Allergic reactions.* Some patients have had allergic reactions to ustekinumab. If you develop a severe rash, a swollen face, or have difficulty breathing while taking ustekinumab, attend a hospital A & E department and make sure that your dermatologist is informed.
- *Cancers.* Many drugs that decrease the activity of the immune system can increase the chance of getting a cancer. The risk is not exactly known at this time, but is likely to be low. Your dermatologist should be consulted if you have any concerns.
- *Latex allergy.* Latex is present in the needle cover of the pre-filled syringe.

Cardiac events and nervous system diseases are much less reported than with other biologics.

Before you start taking ustekinumab, your dermatologist will go through a medical checklist for the following:

- *Tuberculosis* or close contact with someone who has had it. If you develop any symptoms of tuberculosis (e.g. a dry cough that doesn't go away, weight loss, fever, night sweats) call your doctor. You will need to be examined for tuberculosis and have a skin test.
- *Hepatitis or an HIV infection*, or if you think you are at risk of having these.
- If you are scheduled to have *major surgery*.

- If you are scheduled to have any type of vaccination.

You should make sure that you have any regular tests (e.g. with cervical smears and mammograms) to screen for common cancers if you are at the age when these are recommended.

What will happen if I need an operation or dental surgery?

Ustekinumab may increase your risk of getting an infection after a surgical procedure. You must tell the doctor or dentist that you are taking ustekinumab before the operation or dental surgery.

How will I be monitored for the side effects of ustekinumab treatment?

You will probably have a chest X-ray and blood tests before treatment starts; blood checks need only be repeated 3 months after commencing ustekinumab, and then every 3-6 months. Monitoring your response and looking out for side effects will take place at regular clinic visits.

The BAD Biologic Interventions Register (BADBIR)

Because ustekinumab treatment for psoriasis is relatively new, you will be invited to take part in a national register if it is prescribed for you. This register will collect valuable information on side effects and treatment benefits and will help inform doctors on how best to use ustekinumab and similar drugs. No information will be passed to the register without your informed consent.

Can I have immunisations (vaccinations) whilst on ustekinumab?

You should not receive any of the 'live' vaccines such as those for measles, mumps and rubella (German measles), yellow fever and polio (there is, however, an 'inactivated' polio vaccine available). 'Inactivated' vaccines are safe, although they may not work as well if you are on a biological treatment such as ustekinumab.

If you require immunisation with a live vaccine, ustekinumab should be stopped for at least 6 months before and until 2 weeks after the vaccination. Pneumovax and annual influenza (including swine flu) vaccinations are safe and are recommended; however, the new nasal flu vaccination is live and should not be given with ustekinumab.

Does ustekinumab affect pregnancy?

Ustekinumab has not been used in pregnant women or nursing mothers, and so we do not know what its effects are on unborn children or babies who are being breast fed. You should avoid getting pregnant on this treatment. Please tell your doctor if you become pregnant or are thinking about becoming pregnant.

May I drink alcohol while I am taking ustekinumab?

There is no known interaction between alcohol and ustekinumab but it is well recognised that alcohol can make your psoriasis worse.

Can I take other medicines at the same time as ustekinumab?

Most medicines are safe to take with ustekinumab. However, it is important that your GP and other doctors are aware that you are taking it if any new medicine is prescribed. Your GP and dermatologist should be aware of all your medications, including ones you buy at a pharmacy or health shop, including supplements and herbal medicines. If you are taking other immunosuppressant medicines (medicines which suppress the immune system) this should be discussed with your dermatologist.

Can I sunbathe?

Sunbeds and sunbathing should be avoided to reduce the risk of skin cancer.

Where can I get more information about ustekinumab?

This information sheet does not list all of the side effects of ustekinumab. If you want to know more about ustekinumab, or if you are worried about your treatment, you should speak to your doctor, specialist nurse or pharmacist. For fuller details, look at the drug information sheet which comes as an insert with the ustekinumab pack.

Alternatively, visit the website <http://www.stelarainfo.com/>.

For details of source materials used please contact the Clinical Standards Unit (clinicalstandards@bad.org.uk).

This leaflet aims to provide accurate information about the subject and is a consensus of the views held by representatives of the British Association of Dermatologists: individual patient circumstances may differ, which might alter both the advice and course of therapy given to you by your doctor.

This leaflet has been assessed for readability by the British Association of Dermatologists' Patient Information Lay Review Panel

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