



SECUKINUMAB

What are the aims of this leaflet?

This leaflet has been written to help you understand more about secukinumab (Cosentyx™). It tells you what it is, how it is used to treat psoriasis, important safety considerations including potential side effects, and where you can find out more about it.

What is secukinumab and how does it work?

Secukinumab 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 blocks the activity of a naturally occurring chemical 'cytokine' in the body called interleukin-17a (IL-17a). We know that psoriatic plaques contain high levels of IL-17a, and that it drives inflammation in the skin, leading to redness, thickening and flaking.

What conditions are treated with secukinumab?

Secukinumab has only been authorised for use in the treatment of psoriasis.

Why have I been selected for treatment with secukinumab?

The use of secukinumab is reserved for patients who have severe psoriasis and meet criteria based on national guidelines. This includes failure to improve on standard treatments such as methotrexate, ciclosporin, or ultraviolet light therapy. If there are safety reasons why you cannot receive these standard treatments, or they have been tried but you could not tolerate them, then secukinumab can be considered as the next option.

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

The effect of secukinumab is not seen immediately. It may take several weeks before you see an improvement of your psoriasis. In clinical trials, 8 out of 10 patients showed significant improvement by 12 weeks.

How do I take secukinumab?

Secukinumab is given via an injection under your skin (subcutaneously). It is delivered as either a pre-filled syringe which you manually inject, or a pen device which automatically injects the drug. Your doctor will help you decide which device is best suited for you. If you will be giving your own injections, a nurse or a doctor will demonstrate the correct technique to you. Injections are made under the skin of the stomach, thighs or upper outer arms. You will be provided with sharps bins so that you can dispose of your syringes and needles safely. Secukinumab must be stored in a refrigerator (at 2-8°C). If you are travelling with, or transporting your treatment, this requires a cool box or cool bag with icepacks to maintain the recommended temperature.

What dose should I take?

The recommended dose is 300 mg by subcutaneous injection and this is given by two injections of 150 mg. After the first dose you will continue to receive weekly injections for another four weeks, followed by monthly injections thereafter. The dosage given always remains the same. After 12 weeks of treatment, your dermatologist will assess whether secukinumab is working adequately or not, and therefore whether you should continue with treatment. Secukinumab is intended as a long-term treatment to maintain control of your psoriasis.

What are the possible side effects of secukinumab?

Most of the side effects reported during clinical trials of secukinumab were mild, easily manageable, and did not require discontinuation of the treatment.

Mild:

- reaction at the injection site. 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, contact your dermatologist.
- cold symptoms (upper respiratory tract infection)
- sore throat (nasopharyngitis)
- stuffy nose (rhinitis)

- oral thrush (candidiasis)
- hives (urticaria)
- diarrhoea
- headache
- aching joints (arthralgia)
- cold sores

Serious or severe:

- *Serious infections* – there is a possibility that secukinumab 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, acquired immunodeficiency syndrome (AIDS), or viral hepatitis. Try to avoid close contact with anyone with a bad cold, influenza or chest infections, and wash your hands frequently when taking this medication. Avoid dairy foods that are not pasteurised, camembert, brie and blue cheeses, pâté or eggs, meat or poultry that are not adequately cooked and thus pose a risk of salmonella infection. Contact your doctor if you get an infection, or any symptom or sign of an infection, including: fever, lethargy, cough, influenza-like symptoms, burning on passing urine, dental problems, red or painful skin, and open sores on your body. Your dermatologist may suggest discontinuing secukinumab temporarily.
- *Blood problems* - some patients in clinical trials were found to have problems producing enough of the blood cells that help to fight infections. If you develop a fever that does not settle, bruise or bleed very easily, or look very pale, contact your doctor.
- *Allergic reactions* - some patients in clinical trials have had allergic reactions to secukinumab. If you develop a severe rash, a swollen face, or difficulty with breathing while taking secukinumab, you must go to an Accident & Emergency department immediately and make sure that your dermatologist is informed.

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

- Tuberculosis – you will be asked if you have had this in the past or been in close contact with someone else who has had it. A screening blood test for tuberculosis and a chest X-ray will be checked before you

start treatment. You will also be monitored for signs and symptoms of tuberculosis during treatment. For example, a dry cough that doesn't go away, weight loss, fever, and night sweats. Inform your doctor if you experience any of these.

- Hepatitis or HIV infection – you may be screened for these with a blood test.
- Crohn's disease – there is some suggestion that secukinumab may cause a flare of this condition.
- If you plan to have any major surgery.
- If you plan to have any type of vaccination.
- Latex allergy – the removable caps on both the pre-filled syringe and pen contain latex derivative which may cause reaction in latex-sensitive individuals.

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

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

Secukinumab may increase your risk of getting an infection after a surgical procedure. You must tell the doctor or dentist that you are taking secukinumab.

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

Blood tests are required before you start secukinumab, then it is recommended that they are repeated after 3 months. After this you are likely to only need blood tests every 6 months. At your clinic appointments your skin will be examined and you will be asked questions in order to assess your response to treatment. You will also be asked about side effects at each clinic visit.

The BAD Biologic Interventions Register (BADBIR)

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

Can I have immunisations (vaccinations) whilst on secukinumab?

Patients on secukinumab should not be given any 'live' vaccines such as those for polio, rubella (German measles) and yellow fever. If you require immunisation with a live vaccine, secukinumab should be stopped for at least 6 months before and not restarted for at least 2 weeks after the vaccination. 'Inactivated' vaccines (e.g. Pneumovax) are safe but you may not produce a sufficient immune response to protect you from what you are being vaccinated against.

Although annual flu vaccination by injection is safe and recommended, the flu vaccine administered through the nose has live virus and hence should be avoided.

Does secukinumab affect pregnancy?

It is not known whether secukinumab has any adverse effect on the unborn child or babies being breast fed. Therefore as a precaution, secukinumab should be avoided in pregnancy and during breastfeeding. It is important to inform your dermatologist if you are pregnant or planning to become pregnant. Otherwise it is recommended that appropriate contraception is used. The effect of secukinumab continues for a time after stopping treatment, so it is important that this is taken into account also.

Can I travel abroad while taking secukinumab?

Please discuss with your dermatologist if you are planning to travel abroad. Depending on the length of your travel plans, you may need a cool box to take the medication with you. Depending on where you are travelling, precautions may need to be taken against infections. Your dermatologist should be able to advise you on this.

May I drink alcohol while I am taking secukinumab?

There is no known interaction between alcohol and secukinumab. It is already known that excess alcohol can cause a flare of psoriasis, so it is best to avoid this.

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

Most medicines are safe to take with secukinumab. However, it is important that your GP and other doctors are aware that you are taking it if any new drug is prescribed. Your GP and dermatologist should be aware of all your medications, including over-the-counter ones, dietary supplements, and

herbal medicines. You should not take other immunosuppressives (medicines which lower the immune system) while you are on secukinumab.

Where can I find out more about secukinumab?

This information sheet does not list all of the side effects of secukinumab. If you wish to find out more about secukinumab, or if you are worried about your treatment, you should speak to your doctor, specialist nurse or pharmacist.

For further details, look at the drug information sheet which comes as an insert with your prescription for secukinumab.

Or visit the website <http://www.cosentyx.com/>

The Psoriasis Association

<https://www.psoriasis-association.org.uk/>

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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