About your medication

for people with psoriatic arthritis or axial spondyloarthritis

This material is intended for patients who have been prescribed **Cosentyx®** (secukinumab).

October 2024 | IE11294688

Contents

What is Cosentyx and what is it used for	3
What you need to know before you use your medication	4
How to take your medication	7
Dosing Guide	9
Possible side effects	10
How to store and dispose of your medication	12
Glossary	13

October 2024 | IE11294688

What is Cosentyx® and what is it used for

Cosentyx® (secukinumab) is a medicine that is used to treat psoriatic arthritis and axial spondyloarthritis in adults. It contains the active substance secukinumab.

It is an immunosuppressant and a biologic.

Immunosuppressant drugs stop your immune system from attacking healthy cells.

Biologic drugs are made in a laboratory from living cells. Most drugs are chemical, but biologics are based on protein. Traditional systemic drugs for treating autoimmune diseases generally affect the entire immune system. Biologic drugs such as this medicine target specific parts of the immune system.

This medication belongs to a group of medicines called interleukin (IL) inhibitors. This medicine works by neutralising the activity of a protein called IL-17A, which plays an important role in causing inflammation in diseases such as psoriatic arthritis and axial spondyloarthritis.

Psoriatic arthritis is an inflammatory disease of the joints, often accompanied by psoriasis. Axial Spondyloarthritis is an umbrella term used to describe two conditions; non-radiographic axial spondyloarthritis and ankylosing spondylitis. Both of these conditions are inflammatory diseases primarily affecting the spine which cause inflammation of the spinal joints. Throughout this booklet we will use the term "axial spondyloarthritis" to refer to both conditions.

Using this medicine may benefit you by improving your physical functioning and reducing your joint and skin symptoms.

It can be used alone or with another medicine called methotrexate.

October 2024 | IE11294688

What you need to know before you use this medicine

You should not use this medicine:

- **If you are allergic** to secukinumab or any of the other ingredients of this medicine (listed in section 6 of your patient information leaflet that comes with your SensoReady® 150mg or UnoReady® 300mg pen).
- If you think you may be allergic, ask your doctor for advice before using this medicine
- **If you have an active infection,** which your doctor thinks is important.

You might not be able to use this medicine if you have some illnesses.

Tell your doctor or pharmacist before using this medicine:

- If you have or previously had a hepatitis B infection. This medicine may cause a reactivation of the infection. Tell your doctor if you notice any of the following symptoms: worsening tiredness, yellowing of the skin or white part of the eyes, dark urine, loss of appetite, nausea and/or pain in the upper right side of the stomach area
- If you currently have an infection or if you have long-term or repeated infections
- If you have tuberculosis
- If you have ever had an allergic reaction to latex
- If you have Inflammatory Bowel Disease, such as Crohn's Disease or Ulcerative Colitis

- If you have recently had a vaccination or if you are due to have a vaccination during treatment with this medicine
- If you are receiving any other treatment for psoriatic arthritis or axial spondyloarthritis, such as another immunosuppressant or phototherapy with ultraviolet (UV) light

Inflammatory bowel disease (Crohn's disease or Ulcerative Colitis)

Stop using this medicine and tell your doctor or seek medical help immediately if you notice abdominal cramps and pain, diarrhoea, weight loss, blood in the stool or any other signs of bowel problems.

Look out for infections and allergic reactions

This medicine can potentially cause serious side effects, including infections and allergic reactions.
You **must** look out for signs of these conditions while you are taking this medicine.

Stop using this medicine and tell your doctor or seek medical help immediately if you notice any signs indicating a possible serious infection or an allergic reaction. Such signs are listed under "Serious side effects" in section 4 of your patient information leaflet that comes with your SensoReady® 150mg or UnoReady® 300mg pen.

Children and adolescents

This medicine is not recommended for use in psoriatic arthritis or axial spondyloarthritis for children or adolescents (under 18 years of age) because it has not been studied in this age group.

Other medicines and Cosentyx

Tell your doctor or pharmacist:

- If you are taking, have recently taken or might take any other medicines
- If you have recently had or are due to have a vaccination

You should not be given certain types of vaccines (live vaccines) while using this medicine.

Pregnancy

Talk to your doctor if you are pregnant, think you may be pregnant or are planning to have a baby. It is preferable to avoid the use of this medicine in pregnancy. The effects of this medicine in pregnant women are not known. If you are a woman of childbearing age, you are advised to avoid becoming pregnant and must **use adequate contraception while using this medicine and for at least 20 weeks (5 months) after the last dose.**

Breastfeeding

Talk to your doctor if you are breastfeeding or are planning to breastfeed. You and your doctor should decide if you will breastfeed or use this medicine. You should not do both. After using this medicine you **should not breastfeed for at least 20 weeks (5 months) after your last dose**.

Driving and using machines

This medicine has no or negligible influence on the ability to drive and use machines.

How to take this medicine

This medicine is given as a subcutaneous injection. This is an injection that goes under your skin. You and your doctor should decide if you should inject this medicine yourself or if someone should do it for you.

It is important not to try to inject yourself until you have been trained by your doctor, nurse or pharmacist. A caregiver may also give you your injection after proper training.

Your **Medication starter kit** includes the **Self-injection guide**. This guide gives you step-by-step instructions on how to inject yourself using the SensoReady® 150mg or UnoReady® 300mg pen. Use this guide if you need to remind yourself how to inject correctly. Remember, do not start injecting yourself until you have been trained.

Instructions on how to inject yourself using the SensoReady® 150mg or UnoReady® 300mg pen are also available in the patient information leaflet that comes with your SensoReady® 150mg or UnoReady® 300mg pen.

Always use this medicine exactly as your doctor has told you. Check with your doctor, nurse or pharmacist if you are not sure.

October 2024 | IE11294688

How much of this medication is given and for how long?

Your doctor will decide how much of this medication you need and for how long.

If you are prescribed **Cosentyx 150mg dose** you will take o**ne injection of 150mg using the SensoReady® 150mg pen.**

If you are prescribed **Cosentyx 300mg dose** you will take **one injection of 300mg using the UnoReady® 300mg pen or two injections of the SensoReady® 150mg pen.**

When you start this medicine you will have **one dose a week for 5 weeks** (5 weekly). **After this you will have one dose each month** (monthly), which is called a maintenance dose.

This medicine is for long-term treatment. Your doctor will regularly monitor your condition to check that the treatment is having the desired effect.

If you use more of this medicine than you should

If you have received more of this medicine than you should or the dose has been administered sooner than according to your doctor's prescription, inform your doctor.

If you forget to use take your medicine

If you have forgotten to inject a dose of this medicine, inject the next dose as soon as you remember. Then talk to your doctor to discuss when you should inject the next dose.

If you stop using this medicine

It is not dangerous to stop using this medicine. However, if you stop, your psoriatic arthritis or axial spondyloarthritis symptoms may come back.

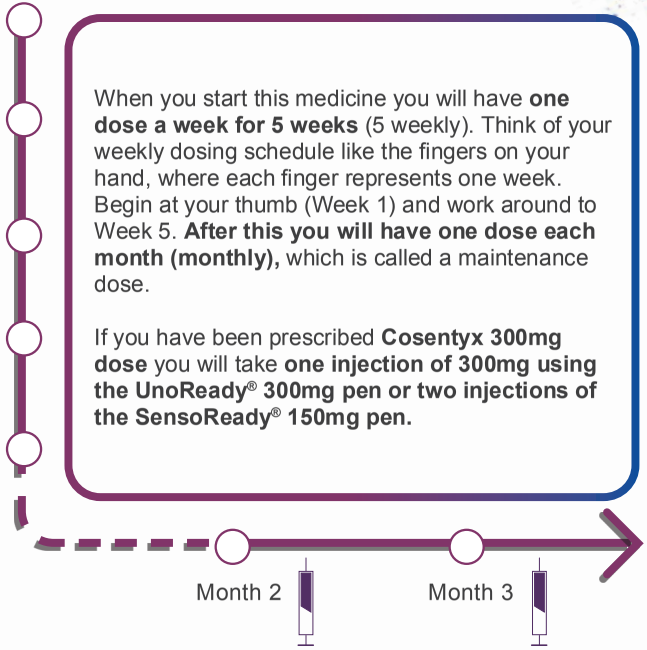
If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

Dosing Guide



When you start this medicine you will have **one dose a week for 5 weeks** (5 weekly). Think of your weekly dosing schedule like the fingers on your hand, where each finger represents one week. Begin at your thumb (Week 1) and work around to Week 5. **After this you will have one dose each month (monthly),** which is called a maintenance dose.

If you have been prescribed **Cosentyx 300mg dose** you will take **one injection of 300mg using the UnoReady® 300mg pen or two injections of the SensoReady® 150mg pen.**



October 2024 | IE11294688

Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

SERIOUS SIDE EFFECTS

Stop using this medicine and tell your doctor or seek medical help immediately if you get any of the following side effects. Your doctor will decide if and when you may restart the treatment:

Signs of possible serious infection may include:

- Fever, flu-like symptoms, night sweats
- Feeling tired or short of breath, cough which will not go away
- Warm, red and painful skin, or a painful skin rash with blisters
- Burning sensation when passing urine

Signs of serious allergic reaction may include:

- Difficulty breathing or swallowing
- Low blood pressure, which can cause dizziness or light headedness
- Swelling of the face, lips, tongue or throat
- Severe itching of the skin, with a red rash or raised bumps

OTHER SIDE EFFECTS

Most of the following side effects are mild to moderate. If any of these side effects becomes severe, tell your doctor, pharmacist or nurse.

Some side effects are very common (may affect more than 1 in 10 people):

- Upper respiratory tract infections with symptoms such as sore throat and stuffy nose (nasopharyngitis, rhinitis)

Some side effects are common (may affect up to 1 in 10 people):

- Cold sores (oral herpes)
- Diarrhoea
- Runny nose (rhinorrhea)
- Headache
- Fatigue
- Nausea
- Itchy, red and dry skin (eczema)

Some side effects are uncommon (may affect up to 1 in 100 people):

- Oral thrush (oral candidiasis)

  Signs of oral thrush may include:

  - *White patches (plaques) in the mouth that can often be wiped off, leaving behind red areas that may bleed*
  - *Loss of taste/unpleasant taste in the mouth*
  - *Redness inside the mouth and throat*
  - *Cracks at the corners of the mouth*

October 2024 | IE11294688

- *Painful, burning sensation in the mouth*

If you develop oral thrush, you may need to take tablets to treat this. If you develop any of the above symptoms please contact your doctor, GP, nurse or pharmacist immediately so that they can decide if you require treatment

- Signs of low levels of white blood cells, such as fever, sore throat or mouth ulcers due to infections (neutropenia)
- Infection of the external ear (otitis externa)
- Discharge from the eye with itching, redness and swelling (conjunctivitis)
- Itchy rash (urticaria)
- Lower respiratory tract infections
- Abdominal cramps and pain, diarrhoea, weight loss or blood in the stool (signs of bowel problems)
- Small, itchy blisters on the palms of hands, soles of feet and edges of the fingers and toes (dyshidrotic eczema)
- Athlete's foot (tinea pedis)

Some side effects are rare (may affect up to 1 in 1,000 people):

- Severe allergic reaction with shock (anaphylactic reactions)
- Redness and shedding of skin over a larger area of the body (>90% of the body surface), which may be itchy or painful and may be accompanied by fever (exfoliative dermatitis)
- Inflammation of small blood vessels, which can lead to a skin rash with small red or purple bumps (vasculitis)
- Swelling of the neck, face, mouth or throat which may lead to difficulty swallowing or breathing (angioedema)

Frequency of some side effects is not known (cannot be estimated from the available data):

- Fungal infections of the skin and mucous membranes (including oesophageal candidiasis)
- Painful swelling and skin ulceration (pyoderma gangrenosum)

REPORTING OF SIDE EFFECTS

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in your patient information leaflet. You can also report side effects directly to the Health Products Regulatory Authority (HPRA) and to Novartis Ireland. You can find their contact details on the back page of this booklet.

By reporting side effects you can help provide more information on the safety of this medicine.

How to store and dispose of this medicine

Keep this medicine out of the sight and reach of children.

How do I store this medicine?

- Your SensoReady® 150mg or UnoReady® 300mg pen comes in a sealed box. There is one pen in each box. Keep the box sealed until you use the medicine. This protects it from light.
- Keep your medicine in the refrigerator between 2°C and 8°C. Please note, if necessary, this medicine can be left out of the refrigerator for up to 4 days at room temperature, not above 30°C.
- Never freeze or shake your SensoReady® 150mg or UnoReady® 300mg pen.
- Do not use your SensoReady® 150mg or UnoReady® 300mg pen if the liquid contains particles that are easy to see; is cloudy; or is very brown.

How long can I store this medicine for?

- There is an expiry date "EXP" on the box that your SensoReady® 150mg or UnoReady® 300mg pen comes in, and on the label on your pen.
- **Do not store or use this medicine after its expiry date.**

Can I reuse my SensoReady® 150mg or UnoReady® 300mg pen?

- No. You can only use a SensoReady® 150mg or UnoReady® 300mg pen once. Then you must put it in a sharps disposal container, which is a special container for getting rid of needles and other medical waste. Never try to reuse your SensoReady® 150mg or UnoReady® 300mg pen.

What should I do if I do not have a sharps disposal container?

- If you do not have a sharps disposal container, you should contact your healthcare professional and they will arrange to get you one.

October 2024 | IE11294688

Glossary

Antibody

An antibody is your body's way of fighting off infections. Antibodies are Y-shaped proteins that identify and neutralise foreign objects such as bacteria and viruses.

Autoimmune disease

You get autoimmune disease when your body attacks and damages healthy cells and tissues in your body. Autoimmune diseases are usually treated with medicines that change the way your immune system works.

Immune system

The immune system is the body's own complex defence system and plays an important role in psoriatic arthritis and axial spondyloarthritis. In psoriatic arthritis and axial spondyloarthritis, the immune system stops working correctly and can lead to inflammation and joint damage.

Interleukin-17A

Interleukin-17A is a protein made by your immune system. If you have psoriatic arthrirtis or axial spondyloarthritis, you will have higher than normal levels of interleukin-17A in your body.

Subcutaneous injection

Subcutaneous injections are injections that are administered underneath the skin.

Secukinumab

Secukinumab is the active substance in this medicine. Secukinumab is an antibody that targets IL-17A. If you have psoriatic arthritis or axial spondyloarthritis, you will have higher than normal levels of interleukin-17A in your body.

October 2024 | IE11294688

Who to contact in case of side effects and/or product complaints

If you get any side effects, talk to your doctor, pharmacist or nurse. By reporting side effects, you can help provide more information on the safety of this medicine.

You can report side effects directly to HPRA Pharmacovigilance, at www.hpra.ie.

Side effects can also be reported to Novartis preferably at www.novartis.com/report, by emailing drugsafety.dublin@novartis.com or by calling (01) 2080 612.



NOVARTIS

October 2024 | IE11294688