Package leaflet: Information for the user

Cosentyx® 150 mg solution for injection in pre-filled pen

secukinumab

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Cosentyx is and what it is used for
2. What you need to know before you use Cosentyx
3. How to use Cosentyx
4. Possible side effects
5. How to store Cosentyx
6. Contents of the pack and other information

1. What Cosentyx is and what it is used for

Cosentyx contains the active substance secukinumab. Secukinumab is a monoclonal antibody which belongs to a group of medicines called interleukin (IL) inhibitors. This medicine works by neutralising the activity of a protein called IL-17A, which is present at increased levels in diseases such as psoriasis, hidradenitis suppurativa, psoriatic arthritis and axial spondyloarthritis.

Cosentyx is used for the treatment of the following inflammatory diseases:
- Plaque psoriasis
- Hidradenitis suppurativa
- Psoriatic arthritis
- Axial spondyloarthritis, including ankylosing spondylitis (radiographic axial spondyloarthritis) and non-radiographic axial spondyloarthritis
- Juvenile idiopathic arthritis, including enthesitis-related arthritis and juvenile psoriatic arthritis

Plaque psoriasis
Cosentyx is used to treat a skin condition called “plaque psoriasis”, which causes inflammation affecting the skin. Cosentyx reduces the inflammation and other symptoms of the disease. Cosentyx is used in adults, adolescents and children (6 years of age and older) with moderate to severe plaque psoriasis.

Using Cosentyx in plaque psoriasis will benefit you by leading to improvements of skin clearance and reducing your symptoms such as scaling, itching and pain.

Hidradenitis suppurativa
Cosentyx is used to treat a condition called hidradenitis suppurativa, also sometimes called acne inversa or Verneuil’s disease. This condition is a chronic and painful inflammatory skin disease. Symptoms may include tender nodules (lumps) and abscesses (boils) that may leak pus. It commonly affects specific areas of the skin, such as under the breasts, the armpits, inner thighs, groin and buttocks. Scarring may also occur in affected areas.

Cosentyx can reduce the number of nodules and abscesses you have and the pain that is often associated with the disease. If you have hidradenitis suppurativa you will first be given other medicines. If you do not respond well enough to these medicines, you will be given Cosentyx.

Cosentyx is used in adults with hidradenitis suppurativa and can be used alone or with antibiotics.

Psoriatic arthritis
Cosentyx is used to treat a condition called "psoriatic arthritis". The condition is an inflammatory disease of the joints, often accompanied by psoriasis. If you have active psoriatic arthritis you will first be given other medicines. If you do not respond well enough to these medicines, you will be given Cosentyx to reduce the signs and symptoms of active psoriatic arthritis, improve physical function and slow down the damage to the cartilage and bone of the joints involved in the disease.

Cosentyx is used in adults with active psoriatic arthritis and can be used alone or with another medicine called methotrexate.

Using Cosentyx in psoriatic arthritis will benefit you by reducing the signs and symptoms of the disease, slowing down the damage to the cartilage and bone of the joints and improving your ability to do normal daily activities.

Axial spondyloarthritis, including ankylosing spondylitis (radiographic axial spondyloarthritis) and non-radiographic axial spondyloarthritis
Cosentyx is used to treat conditions called "ankylosing spondylitis" and "non-radiographic axial spondyloarthritis". These conditions are inflammatory diseases primarily affecting the spine which cause inflammation of the spinal joints. If you have ankylosing spondylitis or non-radiographic axial spondyloarthritis you will first be given other medicines. If you do not respond well enough to these medicines, you will be given Cosentyx to reduce the signs and symptoms of the disease, reduce inflammation and improve your physical function.

Cosentyx is used in adults with active ankylosing spondylitis and active non-radiographic axial spondyloarthritis.

Using Cosentyx in ankylosing spondylitis and non-radiographic axial spondyloarthritis will benefit you by reducing the signs and symptoms of your disease and improving your physical function.

Juvenile idiopathic arthritis, including enthesitis-related arthritis and juvenile psoriatic arthritis
Cosentyx is used in patients (6 years of age and older) to treat conditions of the juvenile idiopathic arthritis categories called "enthesitis-related arthritis" and "juvenile psoriatic arthritis". These conditions are inflammatory diseases affecting the joints and the places where tendons join the bone.

Using Cosentyx in enthesitis-related arthritis and juvenile psoriatic arthritis will benefit you (or your child) by reducing the symptoms and improving your (or your child's) physical function.

2. What you need to know before you use Cosentyx

Do not use Cosentyx:
- **if you are allergic** to secukinumab or any of the other ingredients of this medicine (listed in section 6).
  If you think you may be allergic, ask your doctor for advice before using Cosentyx.
- **if you have an active infection** which your doctor thinks is important (for example, active tuberculosis).

Warnings and precautions
Talk to your doctor, nurse or pharmacist before using Cosentyx:
- if you currently have an infection.
- if you have long-term or repeated infections.

- if you have ever had an allergic reaction to latex.
- if you have an inflammatory disease affecting your gut called Crohn's disease.
- if you have an inflammation of your large intestine called ulcerative colitis.
- if you have recently had a vaccination or if you are due to have a vaccination during treatment with Cosentyx.
- if you are receiving any other treatment for psoriasis, such as another immunosuppressant or phototherapy with ultraviolet (UV) light.

Tuberculosis
Talk to your doctor if you have or previously had tuberculosis. Also tell your doctor if you have recently been in close contact with someone who has tuberculosis. Your doctor will evaluate you and may do a test for tuberculosis before you use Cosentyx. If your doctor thinks you are at risk of tuberculosis, you may be given medicines to treat it. If symptoms of tuberculosis (such as persistent cough, weight loss, listlessness or mild fever) appear during treatment with Cosentyx, tell your doctor immediately.

Hepatitis B
Talk to your doctor if you have or previously had a hepatitis B infection. This medicine may cause a reactivation of the infection. Before and during secukinumab treatment, your doctor may check you for signs of 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.

Inflammatory bowel disease (Crohn's disease or ulcerative colitis)
Stop using Cosentyx 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
Cosentyx can potentially cause serious side effects, including infections and allergic reactions. You must look out for signs of these conditions while you are taking Cosentyx.

Stop using Cosentyx 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.

Children and adolescents
Cosentyx is not recommended for children younger than 6 years of age with plaque psoriasis because it has not been studied in this age group.

Cosentyx is not recommended for children younger than 6 years of age with juvenile idiopathic arthritis (enthesitis-related arthritis and juvenile psoriatic arthritis).

Cosentyx is not recommended for children and adolescents (under 18 years of age) in other indications 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 Cosentyx.

Pregnancy, breast-feeding and fertility
- It is preferable to avoid the use of Cosentyx in pregnancy. The effects of this medicine in pregnant women are not known. If you are a woman of childbearing potential, you are advised

to avoid becoming pregnant and must use adequate contraception while using Cosentyx and for at least 20 weeks after the last Cosentyx dose.
Talk to your doctor if you are pregnant, think you may be pregnant or are planning to have a baby.
- Talk to your doctor if you are breast-feeding or are planning to breast-feed. You and your doctor should decide if you will breast-feed or use Cosentyx. You should not do both. After using Cosentyx you should not breast-feed for at least 20 weeks after the last dose.

Driving and using machines
Cosentyx is unlikely to influence your ability to drive and use machines.

3. How to use Cosentyx

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

Cosentyx is given via injection under your skin (known as a subcutaneous injection). You and your doctor should decide if you should inject Cosentyx yourself.

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 Cosentyx injection after proper training.

For detailed instructions on how to inject Cosentyx, see "Instructions for use of the Cosentyx 150 mg SensoReady pen" at the end of this leaflet.

Instructions for use can also be found via the following QR code and web site:
www.cosentyx.eu

How much Cosentyx is given and for how long
Your doctor will decide how much Cosentyx you need and for how long.

Plaque psoriasis
Adult
- The recommended dose is 300 mg by subcutaneous injection.
- Each 300 mg dose **is given as two injections of 150 mg**.

After the first dose you will receive further weekly injections at weeks 1, 2, 3 and 4 followed by monthly injections. Based on your response, further adjustments to your dose may be recommended by your doctor. At each timepoint you will receive a 300 mg dose given as two injections of 150 mg.

Children aged 6 years and older
- The recommended dose is based on body weight as follows:
  - Weight below 25 kg: 75 mg by subcutaneous injection.
  - Weight 25 kg or above and below 50 kg: 75 mg by subcutaneous injection.
  - Weight 50 kg or above: 150 mg by subcutaneous injection.
    Your doctor may increase the dose to 300 mg.
- Each 150 mg dose **is given as one injection of 150 mg**. Other dosage forms/strengths may be available for administration of the 75 mg and 300 mg doses.

After the first dose you will receive further weekly injections at weeks 1, 2, 3 and 4 followed by monthly injections.

Hidradenitis suppurativa
- The recommended dose is 300 mg by subcutaneous injection.
- Each 300 mg dose **is given as two injections of 150 mg.**

After the first dose you will receive further weekly injections at weeks 1, 2, 3 and 4 followed by monthly injections. Based on your response, further adjustments to your dose may be recommended by your doctor.

Psoriatic arthritis
If you have both psoriatic arthritis and also moderate to severe plaque psoriasis, your doctor may adjust the dose recommendation as needed.

For patients who did not respond well to medicines called tumour necrosis factor (TNF) blockers:
- The recommended dose is 300 mg by subcutaneous injection.
- Each 300 mg dose **is given as two injections of 150 mg**.

After the first dose you will receive further weekly injections at weeks 1, 2, 3 and 4 followed by monthly injections. At each timepoint you will receive a 300 mg dose given as two injections of 150 mg.

For other psoriatic arthritis patients:
- The recommended dose is 150 mg by subcutaneous injection.

After the first dose you will receive further weekly injections at weeks 1, 2, 3 and 4 followed by monthly injections.

Based on your response, your doctor may increase your dose to 300 mg.

Ankylosing spondylitis (Radiographic axial spondyloarthritis)
- The recommended dose is 150 mg by subcutaneous injection.

After the first dose you will receive further weekly injections at weeks 1, 2, 3 and 4 followed by monthly injections.

Based on your response, your doctor may increase your dose to 300 mg. Each 300 mg dose is given as two injections of 150 mg.

Non-radiographic axial spondyloarthritis
- The recommended dose is 150 mg by subcutaneous injection.

After the first dose you will receive further weekly injections at weeks 1, 2, 3 and 4 followed by monthly injections.

Juvenile idiopathic arthritis (enthesitis-related arthritis and juvenile psoriatic arthritis)
- The recommended dose is based on body weight as follows:
  - Weight below 50 kg: 75 mg by subcutaneous injection.
  - Weight 50 kg or above: 150 mg by subcutaneous injection.
- Each 150 mg dose **is given as one injection of 150 mg**. Other dosage forms/strengths may be available for administration of the 75 mg dose.

After the first dose you will receive further weekly injections at weeks 1, 2, 3 and 4 followed by monthly injections.

Cosentyx 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 Cosentyx than you should
If you have received more Cosentyx 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 Cosentyx
If you have forgotten to inject a dose of Cosentyx, 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 Cosentyx
It is not dangerous to stop using Cosentyx. However, if you stop, your psoriasis, 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.

4. Possible side effects

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

Serious side effects
Stop using Cosentyx and tell your doctor or seek medical help immediately if you get any of the following side effects:

Possible serious infection - the signs 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.

Serious allergic reaction - the signs 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.

Your doctor will decide if and when you may restart the treatment.

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.

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)

Common (may affect up to 1 in 10 people):
- cold sores (oral herpes)
- diarrhoea
- runny nose (rhinorrhoea)
- headache
- nausea
- fatigue
- itchy, red and dry skin (eczema)

Uncommon (may affect up to 1 in 100 people):
- oral thrush (oral candidiasis)
- 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)

Rare (may affect up to 1 in 1 000 people):
- severe allergic reaction with shock (anaphylactic reaction)
- redness and shedding of skin over a larger area of the body, which may be itchy or painful (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)

Not known (frequency 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 this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

Malta
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

5. How to store Cosentyx

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

Do not use this medicine:
- after the expiry date which is stated on the outer box or the label on the pen after "EXP".
- if the liquid contains easily visible particles, is cloudy or is distinctly brown.

Store the pen sealed in its box to protect from light. Store in the refrigerator between 2°C and 8°C. Do not freeze. Do not shake.
If necessary, Cosentyx can be left out of the refrigerator for a single period of up to 4 days at room temperature, not above 30°C.

This medicine is for single use only.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Cosentyx contains
- The active substance is secukinumab. Each pre-filled pen contains 150 mg secukinumab.
- The other ingredients are trehalose dihydrate, histidine, histidine hydrochloride monohydrate, methionine, polysorbate 80 and water for injections.

What Cosentyx looks like and contents of the pack
Cosentyx solution for injection is a clear liquid. Its colour may vary from colourless to slightly yellow.
Cosentyx 150 mg solution for injection in pre-filled pen is available in unit packs containing 1 or 2 pre-filled pen(s) and in multipacks containing 6 (3 packs of 2) pre-filled pens.
Not all pack sizes may be marketed.

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Manufacturer
Novartis Pharmaceutical Manufacturing GmbH
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This leaflet was last revised in 02/2025.

Other sources of information
Detailed information on this medicine is available on the European Medicines Agency web site: https://www.ema.europa.eu