

Package leaflet: Information for the user

Cosentyx® 75 mg solution for injection in pre-filled syringe

secukinumab

Read all of this leaflet carefully before you (or your child) start using this medicine because it contains important information.

- 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 (or your child) only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours (or your child's).
- If you (or your child) 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 (or your child) 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, psoriatic arthritis and axial spondyloarthritis.

Cosentyx is used for the treatment of the following inflammatory diseases:

- Paediatric plaque psoriasis
- Juvenile idiopathic arthritis, including enthesitis-related arthritis and juvenile psoriatic arthritis

Paediatric 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 adolescents and children (6 years of age and older) with moderate to severe plaque psoriasis.

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

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 (or your child) use Cosentyx

Do not use Cosentyx:

- **if you (or your child) are allergic** to secukinumab or any of the other ingredients of this medicine (listed in section 6).
If you think you (or your child) may be allergic, ask your doctor for advice before using

Cosentyx.

- **if you (or your child) have an active infection** which your doctor thinks is important.

Warnings and precautions

Talk to your doctor, nurse or pharmacist before using Cosentyx:

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

Hepatitis B

Talk to your doctor if you (or your child) 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 (or your child) 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 (or your child) 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 (or your child) are taking Cosentyx.

Stop using Cosentyx and tell your doctor or seek medical help immediately if you (or your child) 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 (or your child) are taking, have recently taken or might take any other medicines.
- if you (or your child) have recently had or are due to have a vaccination. You (or your child) 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 (or your child) are of childbearing potential, you (or your child) 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 (or your child) are pregnant, may be pregnant or are planning to have a baby.

- Talk to your doctor if you (or your child) are breast-feeding or are planning to breast-feed. You and your doctor should decide if you (or your child) will breast-feed or use Cosentyx. You (or your child) should not do both. After using Cosentyx you (or your child) 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 the skin (known as a subcutaneous injection). You and the doctor should decide if, after proper training, you should inject Cosentyx yourself or a caregiver should give the injection.

It is important not to try to inject Cosentyx before being trained by your doctor, nurse or pharmacist.

For detailed instructions on how to inject Cosentyx, see “Instructions for use of Cosentyx 75 mg pre-filled syringe” at the end of this leaflet.

How much Cosentyx is given and for how long

Your doctor will decide how much Cosentyx you (or your child) need and for how long.

Paediatric plaque psoriasis (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 75 mg dose is **given as one injection of 75 mg**. Other dosage forms/strengths may be available for administration of the 150 mg and 300 mg doses.

After the first dose you (or your child) 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 75 mg dose is given as one injection of 75 mg. Other dosage forms/strengths may be available for administration of the 150 mg dose.

After the first dose you (or your child) 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 (or your child's) condition to check that the treatment is having the desired effect.

If you use more Cosentyx than you should

If you (or your child) have received more Cosentyx than you (they) 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 (or your child) remember. Then talk to your doctor to discuss when you should inject the next dose.

If you (or your child) stop using Cosentyx

It is not dangerous to stop using Cosentyx. However, if you stop, your (or your child's) psoriasis 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 (or your child) 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 (or your child) 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 (or your child) 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 via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

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 syringe after "EXP".
- if the liquid contains easily visible particles, is cloudy or is distinctly brown.

Store the syringe 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 syringe contains 75 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 75 mg solution for injection in pre-filled syringe is available in unit packs containing 1 pre-filled syringe and in multipacks containing 3 (3 packs of 1) pre-filled syringes. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

United Kingdom

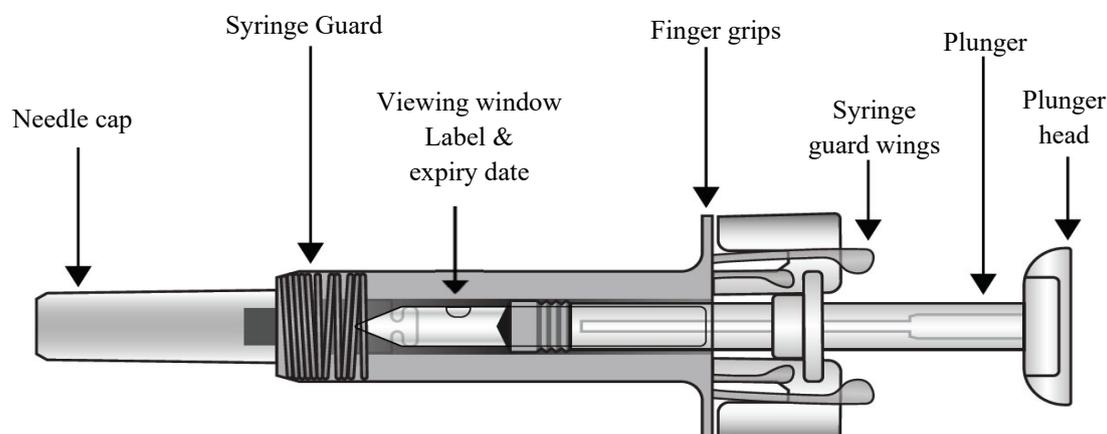
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Instructions for use of Cosentyx 75 mg pre-filled syringe

Read ALL the way through these instructions before injecting. It is important not to try to inject yourself or a person in your care until you have been trained by your doctor, nurse or pharmacist. The box contains one Cosentyx 75 mg pre-filled syringe individually sealed in a plastic blister.

Your Cosentyx 75 mg pre-filled syringe



After the medicine has been injected the syringe guard will be activated to cover the needle. This is intended to aid in the protection of healthcare professionals, patients who self-inject doctor-prescribed medicines, and individuals who assist self-injecting patients from accidental needlestick injuries.

What you additionally need for your injection:

- Alcohol swab.
- Cotton ball or gauze.
- Sharps disposal container.



Important safety information

Caution: Keep the syringe out of the sight and reach of children.

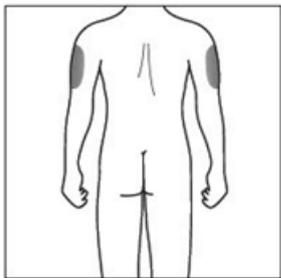
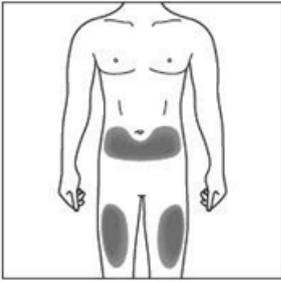
1. The needle cap of the syringe may contain dry rubber (latex), which should not be handled by persons sensitive to this substance.
2. Do not open the sealed outer box until you are ready to use this medicine.
3. Do not use this medicine if either the seal on the outer box or the seal of the blister is broken, as it may not be safe for you to use.
4. Do not use if the syringe has been dropped onto a hard surface or dropped after removing the needle cap.
5. Never leave the syringe lying around where others might tamper with it.
6. Do not shake the syringe.
7. Be careful not to touch the syringe guard wings before use. By touching them, the syringe guard may be activated too early.
8. Do not remove the needle cap until just before you give the injection.
9. The syringe cannot be re-used. Dispose of the used syringe immediately after use in a sharps container.

Storage of the Cosentyx 75 mg pre-filled syringe

1. Store this medicine sealed in its outer box to protect it from light. Store in the refrigerator between 2°C and 8°C. DO NOT FREEZE.
2. Remember to take the syringe out of the refrigerator and allow it to reach room temperature before preparing it for injection (15-30 minutes).
3. Do not use the syringe after the expiry date which is stated on the outer box or syringe label

after “EXP”. If it has expired, return the entire pack to the pharmacy.

The injection site



The injection site is the place on the body where you are going to use the syringe.

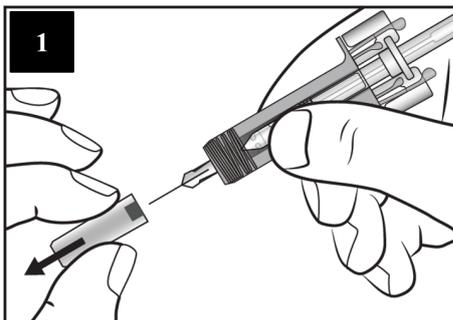
- The recommended site is the front of your thighs. You may also use the lower abdomen, but **not** the area 5 centimetres around the navel (belly button).
- Choose a different site each time you give yourself an injection.
- Do not inject into areas where the skin is tender, bruised, red, scaly or hard. Avoid areas with scars or stretch marks.

If a caregiver is giving you the injection, the outer upper arms may also be used.

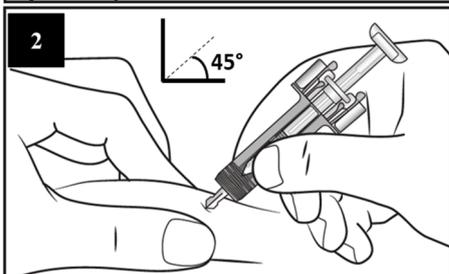
Preparing the Cosentyx 75 mg pre-filled syringe ready for use

1. Take the box containing the syringe out of the refrigerator and leave it **unopened** for about 15-30 minutes so that it reaches room temperature.
2. When you are ready to use the syringe, wash your hands thoroughly with soap and water.
3. Clean the injection site with an alcohol swab.
4. Remove the syringe from the outer box and take it out of the blister by holding the syringe guard body.
5. Inspect the syringe. The liquid should be clear. Its colour may vary from colourless to slightly yellow. You may see a small air bubble, which is normal. **DO NOT USE** if the liquid contains easily visible particles, is cloudy or is distinctly brown. **DO NOT USE** if the syringe is broken. In all these cases, return the entire product pack to the pharmacy.

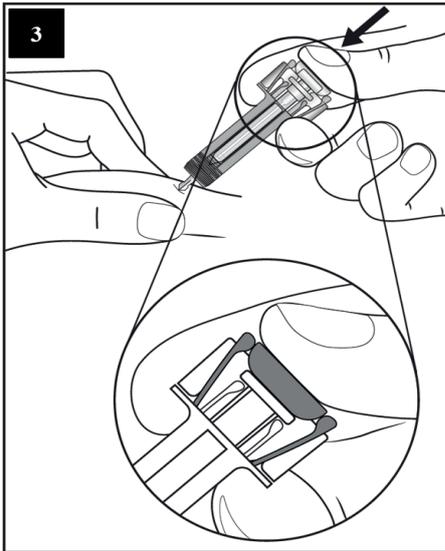
How to use the Cosentyx 75 mg pre-filled syringe



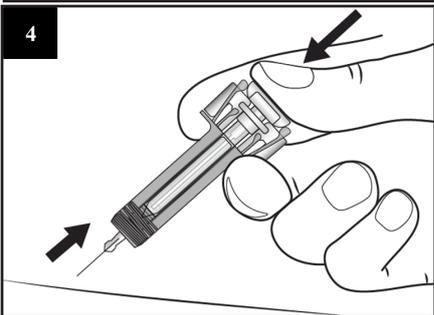
Carefully remove the needle cap from the syringe by holding the syringe guard body. Discard the needle cap. You may see a drop of liquid at the end of the needle. This is normal.



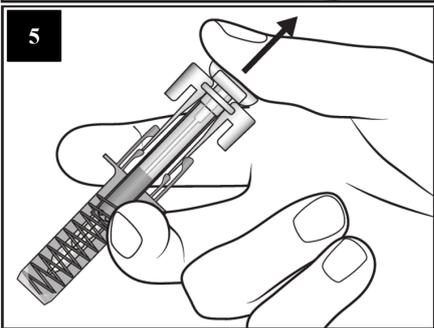
Gently pinch the skin at the injection site and insert the needle as shown. Push the needle all the way in at an angle of approximately 45 degrees to ensure that the medicine can be fully administered.



Hold the syringe as shown. **Slowly** depress the plunger **as far as it will go** so that the plunger head is completely between the syringe guard wings. Keep the plunger pressed fully down while you hold the syringe in place for 5 seconds.



Keep the plunger fully depressed while you carefully lift the needle straight out from the injection site.



Slowly release the plunger and allow the syringe guard to automatically cover the exposed needle.

There may be a small amount of blood at the injection site. You can press a cotton ball or gauze over the injection site and hold it for 10 seconds. Do not rub the injection site. You may cover the injection site with a small adhesive bandage, if needed.

Disposal instructions



Dispose of the used syringe in a sharps container (closable, puncture resistant container). For the safety and health of you and others, needles and used syringes **must never** be re-used.