

# COSENTYX®

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

### 1. Why am I using COSENTYX?

COSENTYX contains the active ingredient secukinumab. COSENTYX is used to treat plaque psoriasis, psoriatic arthritis, ankylosing spondylitis, and non-radiographic axial spondyloarthritis and juvenile idiopathic arthritis (JIA), including Entesitis Related Arthritis (ERA) and Juvenile Psoriatic Arthritis (JPsA).

For more information, see Section [1. Why am I using COSENTYX?](#) in the full CMI.

### 2. What should I know before I use COSENTYX?

Do not use if you have ever had an allergic reaction to secukinumab or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use COSENTYX?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with COSENTYX and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use COSENTYX?

- Your healthcare provider will prescribe the dose of COSENTYX that is right for you. Use COSENTYX exactly as prescribed.
- Do not try to inject COSENTYX yourself until you or your caregiver has been shown how by your healthcare provider.
- If you have forgotten to inject a dose of COSENTYX, do not take a double dose to make up for the dose you missed.

More instructions can be found in Section [4. How do I use COSENTYX?](#) in the full CMI.

### 5. What should I know while using COSENTYX?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Discontinue treatment and tell your doctor or pharmacist immediately if you get any signs or symptoms of a potentially serious infection or an allergic reaction during treatment with COSENTYX.</li><li>• Tell your doctor you are taking COSENTYX before a vaccination as live vaccines are not suitable for you.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop taking your medicine or change dosage without checking with your doctor first.</li><li>• Do not use this medicine if the liquid contains easily visible particles, is cloudy or is distinctly brown.</li><li>• Do not use if the outer box or blister seals are broken, or if it has been dropped with the cap removed.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how COSENTYX affects you.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep it in a refrigerator at 2°C to 8°C. Do not freeze it.</li><li>• 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. Do not put back in the refrigerator after it has reached room temperature. Discard any unused product.</li></ul>

For more information, see Section [5. What should I know while using COSENTYX?](#) in the full CMI.

### 6. Are there any side effects?

All medicines can have side effects although not everybody gets them. The most common side effects of COSENTYX include cold symptoms, diarrhea, and upper respiratory infections. COSENTYX may cause serious allergic reactions.

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking COSENTYX.**

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

# COSENTYX<sup>®</sup> (koe-sen-tix)

Active ingredient(s): *secukinumab*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using COSENTYX. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using COSENTYX.**

Where to find information in this leaflet:

- [1. Why am I using COSENTYX?](#)
- [2. What should I know before I use COSENTYX?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use COSENTYX?](#)
- [5. What should I know while using COSENTYX?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I using COSENTYX?

**COSENTYX contains the active ingredient secukinumab.**

COSENTYX is a fully-human monoclonal antibody and belongs to a group of medicines called interleukin (IL) inhibitors. Monoclonal antibodies are proteins that recognise and bind specifically to certain proteins in the body. COSENTYX works by neutralising the activity of the IL-17A protein, which is present at increased levels in conditions such as psoriasis, psoriatic arthritis, and axial spondyloarthritis. It will reduce the inflammation and other symptoms of the condition.

**COSENTYX is used** for the treatment of the following inflammatory diseases:

- Plaque psoriasis
- Psoriatic arthritis
- Axial spondyloarthritis, including ankylosing spondylitis (axial spondyloarthritis with radiographic damage) and non-radiographic axial spondyloarthritis (axial spondyloarthritis without radiographic damage)

#### Plaque psoriasis

COSENTYX is used to treat a skin condition called 'moderate to severe plaque psoriasis' in patients 6 years and older who are candidates for systemic therapy or phototherapy.

Plaque psoriasis causes inflammation of the skin.

#### 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.

#### Axial spondyloarthritis, including ankylosing spondylitis (axial spondyloarthritis with radiographic damage) and non-radiographic axial spondyloarthritis (axial spondyloarthritis without radiographic damage)

COSENTYX is used to treat a condition called 'ankylosing spondylitis' and 'non-radiographic axial spondyloarthritis' in adults. These conditions are inflammatory diseases primarily affecting the spine which causes inflammation of the spinal joints.

#### Juvenile idiopathic arthritis, including Enthesitis Related Arthritis (ERA) and Juvenile Psoriatic Arthritis (JPsA)

COSENTYX is used to treat a condition called "Juvenile idiopathic arthritis" These conditions are inflammatory diseases affecting the joints and the places where tendons join the bone. In JPsA patients 2 years and older and ERA patients 4 years and older, COSENTYX reduces the symptoms of these diseases and improves their ability to do normal daily activities.

In patients with plaque psoriasis, psoriatic arthritis, axial spondyloarthritis, and juvenile idiopathic arthritis the body produces increased amounts of a protein called IL-17A. This may lead to symptoms such as itching, pain, scaling in psoriasis, swollen and tender joints in psoriatic arthritis, and pain in the spine in axial spondyloarthritis.

### 2. What should I know before I use COSENTYX?

#### Warnings

**Do not use COSENTYX if:**

- you are allergic to secukinumab, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine. Some of the symptoms of an allergic reaction may include:
  - shortness of breath, wheezing or difficulty breathing or swallowing
  - swelling of the face, lips, tongue or other parts of the body
  - rash, itching or hives on the skin

If you think you may be allergic, ask your doctor for advice before using COSENTYX.

- Do not take COSENTYX if you have an active infection which your doctor thinks is important.
- Do not take COSENTYX if there are visible signs of deterioration. If it has expired or is damaged, return it to your pharmacist for disposal.

#### Check with your doctor if you:

- are not sure whether you should start taking this medicine
- have tuberculosis
- have ever been diagnosed with inflammatory bowel disease (Crohn's disease or ulcerative colitis)
- had a recent vaccination or if you will receive a live vaccine during treatment with COSENTYX
- ever had an allergic reaction to latex

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

#### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. COSENTYX is not recommended during pregnancy unless the benefits clearly outweigh the potential risks.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

#### Special populations

- COSENTYX is not recommended for children under 6 years of age with plaque psoriasis because it has not been studied in this age group.
- 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.
- COSENTYX may be used by people aged 65 years and over.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Tell your doctor or pharmacist if you:

- are taking a blood thinning medicine called warfarin.
- are taking, have recently taken or might take any other medicines.
- have recently had or are going to have a vaccination. You should not receive certain types of vaccines (live vaccines) while using COSENTYX. It is recommended that children and adolescents receive all age-

appropriate vaccines according to current guidelines before using COSENTYX.

**Such medicines may interfere with COSENTYX and affect how it works.** You may need different amounts of your medicines, or you may need to take different medicines.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect COSENTYX.** Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

### 4. How do I use COSENTYX?

#### How much to give / use

Your doctor will decide how much COSENTYX you need.

- **Plaque psoriasis**  
In adults, the recommended dose is 300 mg by subcutaneous injection with initial loading dose at Weeks 0, 1, 2, 3, and 4 followed by the same dose every month. If you weigh 90 kgs or higher, further adjustments to your dose may be recommended by your doctor. Each 300 mg dose is given as one subcutaneous injection of 300mg or as two subcutaneous injections of 150 mg.  
In children 6 years and older, the recommended dose is based on body weight and is given by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3, and 4 followed by the same dose every month.  
For children receiving the 75mg dose, the 75mg/0.5mL pre-filled syringe should be used.
- **Psoriatic arthritis**  
The recommended dose is 150 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3, and 4 followed by the same dose every month. Based on your response, your doctor may increase the dose to 300 mg.  
For psoriatic arthritis patients who also have 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 with initial dosing at Weeks 0, 1, 2, 3, and 4 followed by the same dose every month. Each 300 mg dose is given as one subcutaneous injection of 300mg or as two subcutaneous injections of 150 mg.  
COSENTYX may be administered with or without methotrexate.
- **Axial Spondyloarthritis**  
**Ankylosing spondylitis**  
The recommended dose is 150 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3, and 4 followed by the same dose every month. Based on your response, your doctor may increase the dose to 300 mg. Each 300 mg dose is given as one subcutaneous injection of 300mg or as two subcutaneous injections of 150 mg.  
**Non-radiographic axial spondyloarthritis**

With a loading dose: The recommended dose is 150 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3, and 4 followed by the same dose every month.

Without a loading dose: The recommended dose is 150 mg by subcutaneous injection every month.

- Juvenile idiopathic arthritis  
Enthesitis Related (ERA) in children 4 years and older  
The recommended dose is based on body weight and is given by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3, and 4 followed by the same dose every month. For patients weighing > 15 kg and < 50 kg the dose is 75 mg. For patients weighing ≥ 50 kg the dose is 150 mg.  
Juvenile Psoriatic Arthritis (JPsA) in children 2 years and older  
The recommended dose is based on body weight and is given by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3, and 4 followed by the same dose every month. For patients weighing < 50 kg the dose is 75 mg. For patients weighing ≥ 50 kg the dose is 150 mg.
- **Do not exceed the recommended dose.**
- Follow the instructions provided and use COSENTYX until your doctor tells you to stop.

## How to give COSENTYX

**Follow all directions given to you by your doctor, nurse or pharmacist carefully.** They may differ from the information contained in this leaflet.

**Always use COSENTYX as your doctor has told you. You should check with your doctor, nurse or pharmacist if you are not sure.**

COSENTYX is intended for subcutaneous use. This means that it is injected into the fatty tissue just under the skin.

The injection may be given by your doctor or nurse or caregiver or you may be taught how to inject yourself with the medicine.

**You and your doctor should decide if you should inject COSENTYX yourself.**

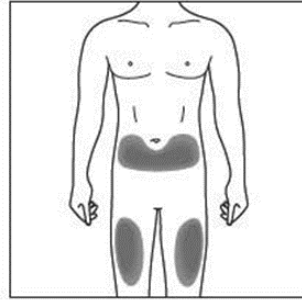
After proper training in subcutaneous injection technique, patients ≥ 12 years old may self-inject COSENTYX or, for all patients ≥ 6 years old, the injection may be injected given by a caregiver if your doctor determines that it is appropriate.

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.

**If you do not understand the instructions on the label ask your doctor or pharmacist for help.**

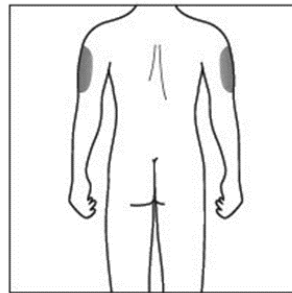
## Choosing the injection sites

The injection sites are where the skin will be pierced to administer the subcutaneous injection.



The recommended site is the front of your thighs. You may also use the lower abdomen, but **not** the area five centimetres around the navel (belly button). Choose a different site each time you give yourself an injection.

If a caregiver is giving you the injection, the outer upper arms may also be used (Shown in grey in the diagram for illustrative purposes).



Do not inject into areas where the skin is tender, bruised, red, scaly or hard. Avoid areas with scars or stretch marks



**Read the enclosed Instructions for Use on how to use COSENTYX all the way through before removing COSENTYX from the refrigerator. These instructions are to help you to inject correctly.**

## How long to use COSENTYX

This is a long-term treatment. Keep taking this medicine for as long as your doctor tells you.

Your doctor will regularly monitor your condition to check that the treatment is having the desired effect.

## 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 are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to have your medicine, ask your pharmacist for some hints.

**Do not take a double dose to make up for the dose you missed.**

## If you use too much COSENTYX

If you think that you have used too much COSENTYX, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (0800 764 766) in New Zealand or (13 11 26) in Australia
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using COSENTYX?

### Things you should do

**Discontinue treatment and tell your doctor or pharmacist immediately if you get any of these symptoms during treatment with COSENTYX.**

**Call your doctor straight away if you:**

- Signs or symptoms of a potentially serious infection. These 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 when passing urine
- Signs or symptoms of an allergic reaction. These may include:
  - difficulty breathing or swallowing
  - low blood pressure, which can cause dizziness or light-headedness
  - swelling of the face, lips, mouth or throat
  - severe itching of the skin, with a red rash or raised bumps
- **Keep all of your doctor's appointments so that your progress can be checked.** Your doctor will do tests from time to time to make sure the medicine is working and to prevent unwanted side effects. Your doctor will decide if and when you may restart the treatment.

- **If you need to be vaccinated, tell your doctor you are taking COSENTYX before you have the vaccination.** Live vaccines will not be suitable for you.
- **If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking COSENTYX.**
- Remind any doctor, dentist or pharmacist you visit that you are using COSENTYX.

### Things you should not do

- Do not stop taking your medicine or change dosage without checking with your doctor first.
- Never leave the prefilled pen lying around where others might tamper with it.
- Do not open the sealed box until you are ready to use COSENTYX.
- Do not use this medicine if the liquid contains easily visible particles, is cloudy or is distinctly brown.
- Do not use the prefilled pen if either the seal on the outer box or the seal of the blister are broken. It may not be safe for you to use.
- Do not shake the prefilled pen.
- Do not use the pen if it has been dropped with the cap removed.
- Do not take it to treat any other complaints unless your doctor tells you to.
- Do not give this medicine to anyone else, even if they have the same condition as you.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how COSENTYX affects you.**

No studies on the effects on the ability to drive and use of machines have been performed on COSENTYX.

### Looking after your medicine

Keep it in a refrigerator at 2°C to 8°C. Do not freeze it.

Store it in the carton in order to protect it from light. Follow the instructions in the carton on how to take care of your medicine properly.

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.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

A locked section of the refrigerator, at least one-and-a-half metres above the ground, is a good place to store COSENTYX.

**Keep it where young children cannot reach it.**

### When to discard your medicine

Do not put back in the refrigerator after it has reached room temperature. Discard any unused product.

Dispose of the used COSENTYX prefilled pens immediately after use in a sharps container. The COSENTYX prefilled pen should never be re-used.

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects although not everybody gets them. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking COSENTYX.**

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• Infection and infestation related such as sore throat, stuffy nose, oral thrush, cold sores, infection of the external ear, discharge from the eye with itching, redness and swelling, and athlete's foot</li> <li>• Allergic reactions related such as runny nose, hives, headache, nausea, and itchy rash</li> <li>• Diarrhoea</li> <li>• Painful period</li> <li>• Small, itchy blisters on the palms of hands, soles of feet and edges of the fingers and toes (dyshidrotic eczema)</li> </ul>	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• Severe allergic reaction with shock (anaphylactic shock)</li> <li>• Signs of low levels of white blood cells such as fever, sore throat or mouth ulcers due to infections (neutropenia)</li> <li>• Symptoms of inflammatory bowel disease such as nausea, diarrhoea, vomiting, abdominal pain and fever. <b>New cases of inflammatory bowel disease or "flare-ups" can happen with COSENTYX, and can sometimes be serious.</b> If you have inflammatory bowel disease (ulcerative colitis or Crohn's disease), tell your doctor if you</li> </ul>	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

have worsening symptoms during treatment with COSENTYX or develop new symptoms of stomach pain or diarrhoea.	
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- The frequency of some side effects cannot be estimated from available data
  - Fungal infections of the skin and mucous membranes (thrush)
  - Painful swelling and skin ulceration (pyoderma gangrenosum)
- COSENTYX may affect the results of some blood tests, including:
  - slight increase in blood cholesterol and blood fat (triglycerides)
  - elevated liver enzymes
- In clinical trials, major adverse cardiovascular events were rarely observed with COSENTYX.

**Ask your doctor or pharmacist to answer any questions you may have. Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects in Australia

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What COSENTYX contains

<b>Active ingredient</b>	secukinumab
<b>Other ingredients</b>	trehalose dihydrate histidine / histidine hydrochloride monohydrate methionine polysorbate 80 water for injection
<b>Potential allergens</b>	This medicine does not contain sucrose, lactose, gluten, tartrazine or any other azo dyes.

**Do not take this medicine if you are allergic to any of these ingredients.**

### **What COSENTYX looks like**

COSENTYX solution for injection is a clear liquid. Its colour may vary from colourless to slightly yellow.

COSENTYX 75 mg/0.5 mL solution for injection is available in packs containing 1 single-use pre-filled syringe (AUST R 353254).

COSENTYX 150 mg/1 mL solution for injection is available in packs containing 1 or 2 single-use pre-filled pens\* (AUST R 218800) or 1 or 2 single-use pre-filled syringes\* (AUST R 218799).

COSENTYX 300 mg/2 mL solution for injection is available in packs containing 1 single-use pre-filled pen (AUST R 353266) or 1 single-use pre-filled syringe\* (AUST R 353265).

\*Not all presentations or pack sizes may be marketed.

### **Who distributes COSENTYX**

#### **Novartis Pharmaceuticals Australia Pty Limited**

ABN 18 004 244 160

54 Waterloo Road

Macquarie Park NSW 2113

Telephone 1 800 671 203

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#### **Novartis New Zealand Limited**

PO Box 99102

Auckland

Free Phone: 0800 354 335

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