NOVARTIS

**COSENTYX® 150 mg/mL solution for injection**

(Solution for injection in a pre-filled syringe or pre-filled pen)

**COSENTYX® 300 mg/2 mL solution for injection**

(Solution for injection in a pre-filled syringe or pre-filled pen)

**Patient Information Leaflet**

| | |
|---|---|
| Document type: | Patient Information Leaflet |
| Document status: | Final |
| Approval date: | 17 August 2026 |

| **Access to the corresponding Professional Information**<br>To access the latest, approved Professional Information, scan the QR code with the camera from a smartphone or smart device.<br>If you are unable to access the Professional Information via the QR code, kindly email your request for the Professional Information to:<br>medinfo.za@novartis.com or call Novartis South Africa on (+27) 011 347 6600. | |
|---|---|

**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS S4**

**COSENTYX® 150 mg/mL Solution for Injection**

Secukinumab

Sugar free

**COSENTYX® 300 mg/2 mL Solution for injection**

Secukinumab

Sugar free

**Read all of this leaflet carefully before you are given COSENTYX®**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist, nurse or other health care provider.
- COSENTYX® has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms 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

### What COSENTYX® is

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, ankylosing spondylitis and hidradenitis suppurativa.

### What COSENTYX® is used for

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

- Plaque psoriasis
- Psoriatic arthritis
- Axial spondyloarthritis (axSpA)
  - Ankylosing spondylitis
  - Non-radiographic axial spondyloarthritis
- Hidradenitis Suppurativa

**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 patients 6 years 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.

**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 (axSpA) with or without radiographic damage**

**Ankylosing spondylitis (AS) & Non-radiographic axial spondyloarthritis (nr-axSpA)**

COSENTYX® is used to treat the conditions called “ankylosing spondylitis” and “non-radiographic axial spondyloarthritis”. These conditions are inflammatory diseases primarily affecting the spine which causes 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 or non-radiographic axial spondyloarthritis.

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

**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.

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

Using COSENTYX® in hidradenitis suppurativa will benefit you by reducing the number of nodules and abscesses you have and the pain that is often associated with the disease.

If you have any questions about COSENTYX®, how it works or why this medicine has been prescribed for you, ask your doctor.

## 2. What you need to know before and while 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.

**Warnings and precautions**

Tell your doctor or pharmacist before using COSENTYX®:

- if you currently have an infection;
- if you have long-term or repeated infections;
- if you have tuberculosis or have had a past history of tuberculosis;
- if you have ever had hepatitis B;

- if you have ever been diagnosed with Crohn's disease;
- if you have 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.

If any of these apply to you, your doctor will decide whether you should be given COSENTYX®.

**Tell your doctor or pharmacist immediately if you get any of these symptoms during treatment with Cosentyx:**

- If you develop itchy rash, dry skin, dry patches, inflamed skin, coin-shaped spots on the skin [dermatitis (including eczema)].
- If you develop severe inflammation of the entire skin surface (dermatitis exfoliative).

**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 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.

**Older people (65 years or above)**

COSENTYX® may be used by people aged 65 years and over with no dose adjustment required.

**Other medicines and COSENTYX®**

Always tell your healthcare professional if you are taking any other medicine, including complementary or traditional medicines.

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®. Children should be brought up to date with all vaccines before starting Cosentyx.

**Pregnancy and breastfeeding and fertility**

COSENTYX® is not to be used during pregnancy.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

If you are breastfeeding or plan to breastfeed your baby, you should not be administered COSENTYX®.

**Driving and using machines**

COSENTYX® is unlikely to influence your ability to drive and use machines.

## 3. How to use COSENTYX®

**COSENTYX® Solution for Injection:**

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 COSENTYX®” in this leaflet.

**How much COSENTYX® is given and for how long**

Your doctor will decide how much COSENTYX® you need and for how long.

*Plaque psoriasis*

In adults the recommended dose is 300 mg by subcutaneous injection.

Each 300 mg dose is given as one subcutaneous injection of 300 mg or as two 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 monthly maintenance dosing.

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

*Psoriatic arthritis*

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.

Each 300 mg dose is given as one subcutaneous injection of 300 mg or 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 one subcutaneous injection of 300 mg or 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.

*Axial spondyloarthritis (axSpA)*

*Ankylosing spondylitis*

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 one subcutaneous injection of 300 mg or 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.

*Hidradenitis Suppurativa*

The recommended dose is 300 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3, and 4 followed by an injection every two weeks.

Each 300 mg dose is given as one subcutaneous injection of 300 mg or two subcutaneous injections of 150 mg.

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**

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

**If you forget to use COSENTYX®**

If you have missed a COSENTYX® injection, talk to your doctor.

**If you stop using COSENTYX®**

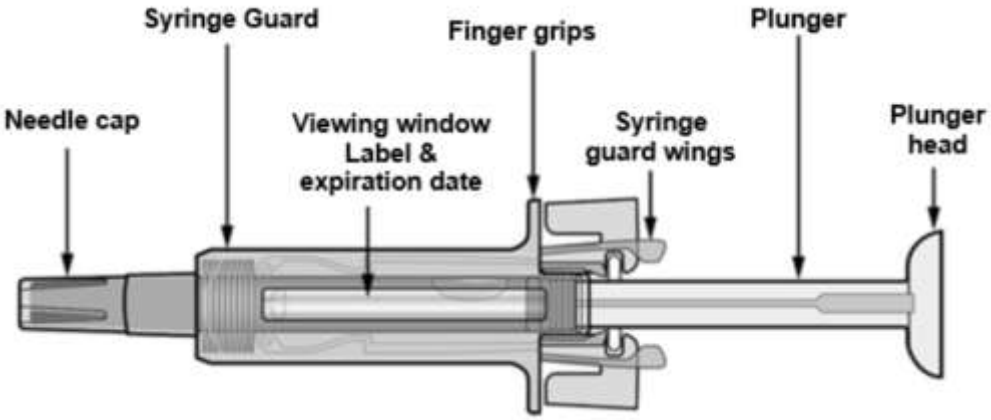
It is not dangerous to stop using COSENTYX®. However, if you stop, your psoriasis, psoriatic arthritis or ankylosing spondylitis symptoms may come back.

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

**Instructions for use of the COSENTYX® 300 mg pre-filled syringe**

Read ALL the way through these instructions before injecting. It is important not to try to inject yourself until you have been trained by your doctor, nurse or pharmacist. The box contains one COSENTYX® 300 mg pre-filled syringe sealed in a plastic blister.

**Your COSENTYX® 300 mg pre-filled syringe**




After the medication has been injected the syringe guard will be activated to cover the needle. This COSENTYX® pre-filled syringe is intended to aid in the protection of healthcare professionals, patients who self-inject doctor prescribed medications, and individuals who assist self-injecting patients from accidental needle sticks**.**

**What you additionally need for your injection:**

| | |
|---|---|
| • Alcohol swab.<br>• Cotton ball or gauze.<br>• Sharps disposal container. |  |

**Important safety information**

**Caution: Keep the COSENTYX® 300 mg pre-filled syringe out of the reach of children.**

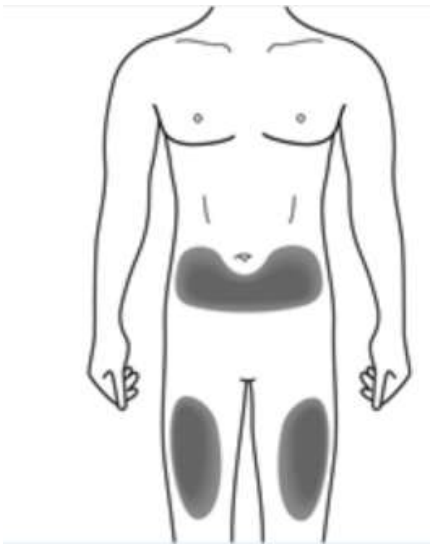
1. Do not open the sealed outer box until you are ready to use the COSENTYX® pre-filled syringe.
2. Do not use the COSENTYX® pre-filled syringe if either the seal on the outer box or the seal of the blister are broken, as it may not be safe for you to use.

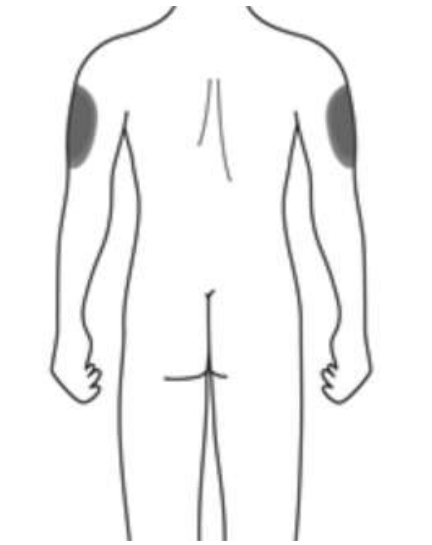
3. Do not use if syringe has been dropped onto a hard surface or dropped after removing the needle cap
4. Never leave the COSENTYX® pre-filled syringe lying around where others might tamper with it.
5. Do not shake the COSENTYX® pre-filled syringe.
6. Be careful not to touch the syringe guard wings before use. By touching them, the syringe guard may be activated too early.
7. Do not remove the needle cap until just before you give the injection.
8. The COSENTYX® pre-filled syringe cannot be re-used. Dispose of the used COSENTYX® pre-filled syringe immediately after use in a sharps container.

**Storage of the COSENTYX® 300 mg pre-filled syringe**

1. Store the COSENTYX® pre-filled syringe 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 COSENTYX® pre-filled syringe out of the refrigerator and allow it to reach room temperature before preparing it for injection (30 to 45 minutes).
3. Do not use the COSENTYX® pre-filled syringe after the expiration date shown on the outer box or syringe label. 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 COSENTYX® pre-filled syringe.

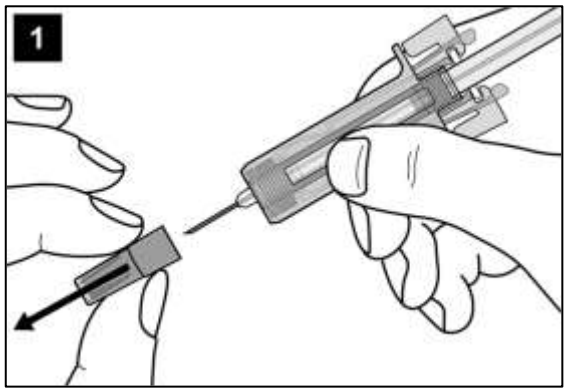
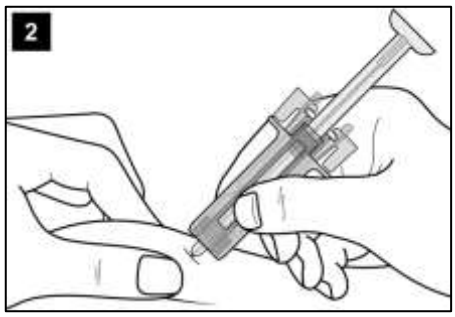
- The recommended site is the front of your thighs. You may also use the lower abdomen, but **not** the area 2 inches (5 cm) around the navel (belly button). If a caregiver is giving you the injection, the outer upper arms may also be used.
- Choose a different site each time you give yourself an injection.
- Do not inject into areas where the skin is tender, bruised, red, scaly or hard. Avoid areas with scars or stretch marks.

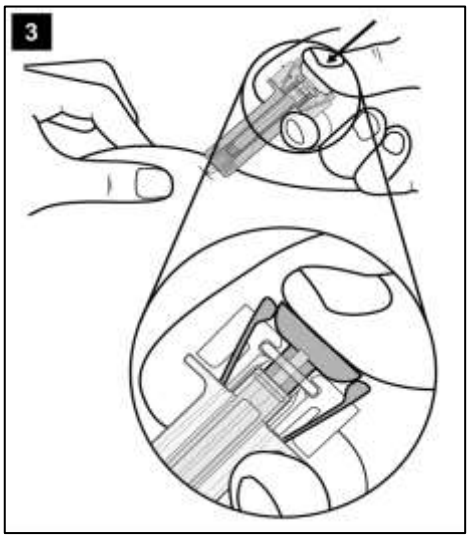
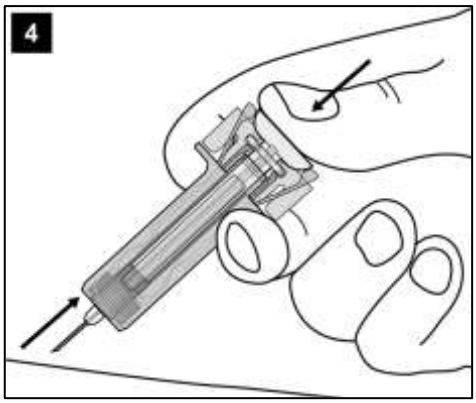
**Preparing the COSENTYX® 300 mg pre-filled syringe ready for use**

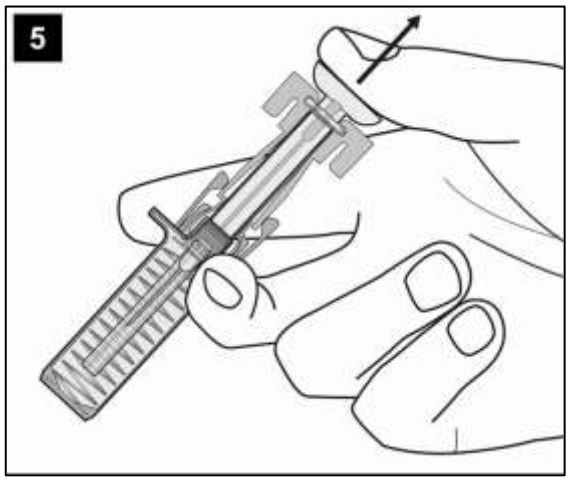
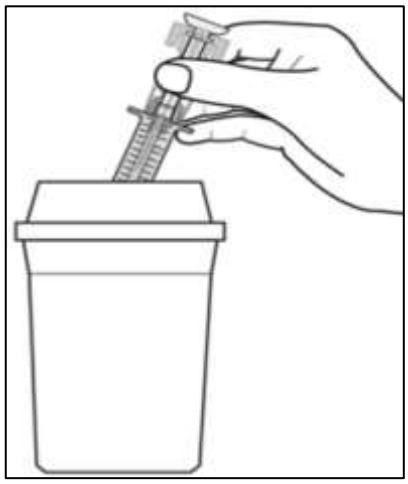
1. Take the box containing the COSENTYX® pre-filled syringe out of the refrigerator and leave it **unopened** for about 30 to 45 minutes so that it reaches room temperature.
2. When you are ready to use the COSENTYX® pre-filled syringe, wash your hands thoroughly with soap and water.
3. Clean the injection site with an alcohol swab.

4. Remove the COSENTYX® pre-filled syringe from the outer box and take it out of the blister by holding the syringe guard body.
5. Inspect the COSENTYX® pre-filled 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 COSENTYX® pre-filled syringe is broken. In all these cases, return the entire product pack to the pharmacy.

**HOW TO USE THE COSENTYX® 300 mg PRE-FILLED SYRINGE**

| | |
|---|---|
|  | Carefully remove the needle cap from the COSENTYX® pre-filled syringe. 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 to ensure that the medication can be fully administered. |

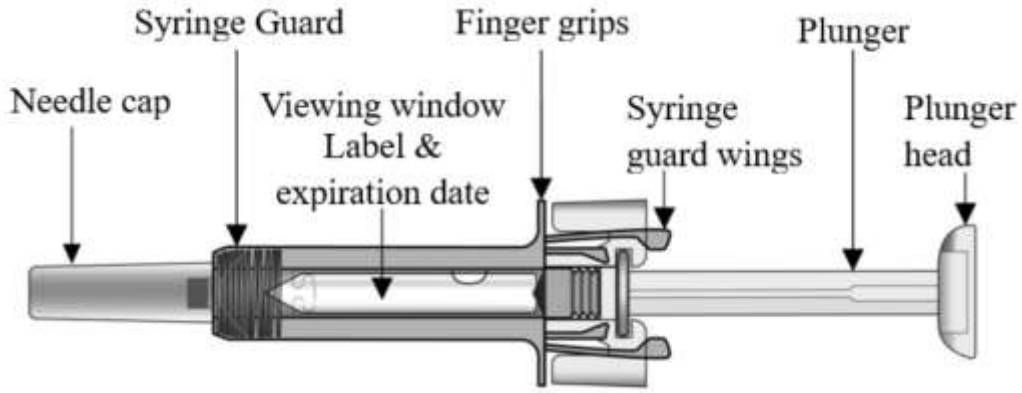
| | |
|---|---|
|  | Holding the COSENTYX® pre-filled syringe as shown, **slowly** depress the plunger **as far as it will go** so that the plunger head is completely between the syringe guard wings.<br><br>Keep the plunger pressed fully down while you hold the syringe in place for 5 seconds. |
|  | **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.<br><br>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 COSENTYX® pre-filled 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. |

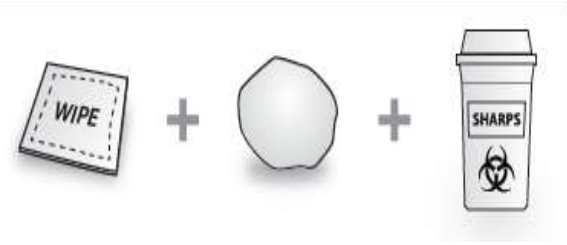
**Instructions for use of the COSENTYX® 150 mg/mL solution for injection prefilled syringe**

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 COSENTYX® pre-filled syringe(s) individually sealed in a plastic blister.

**Your COSENTYX® pre-filled syringe**




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

| | |
|---|---|
| **What you additionally need for your injection:**<br>• Alcohol swab.<br>• Cotton ball or gauze.<br>• Sharps disposal container. |  |

**Important safety information**

**Caution: Keep the COSENTYX® pre-filled syringe out of the reach of children.**

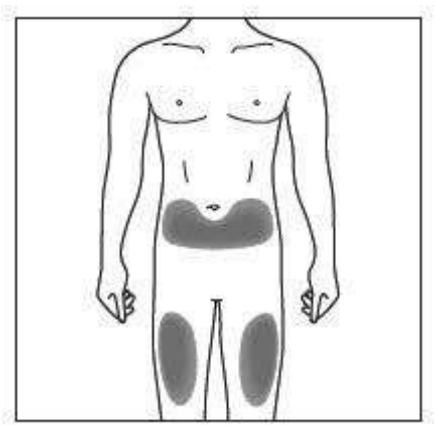
1. The needle cap of the **syringe may contain dry rubber (latex), which** should not be handled by persons sensitive to this substance.

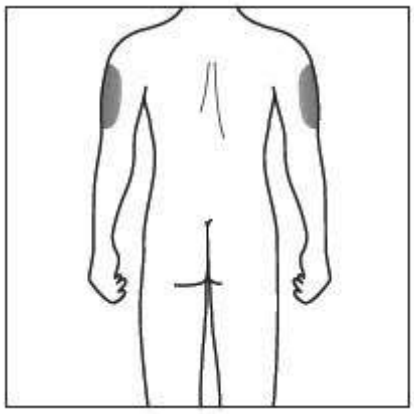
2. Do not open the sealed outer box until you are ready to use this medicine.
3. Do not use this medicine if either the seal on the outer box or the seal of the blister are broken, as it may not be safe for you to use.
4. Do not use if the syringe has been dropped onto a hard surface or dropped after 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 syringes cannot be re-used. Dispose of the used syringe immediately after use in a sharps container.

**Storage of the COSENTYX® 150 mg/mL solution for injection 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 to 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 2 inches (~ 5 cm) around the navel (belly button). If a caregiver is giving you the injection, the outer upper arms may also be used.
- 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.

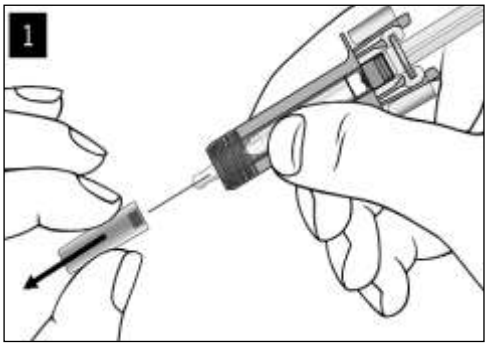
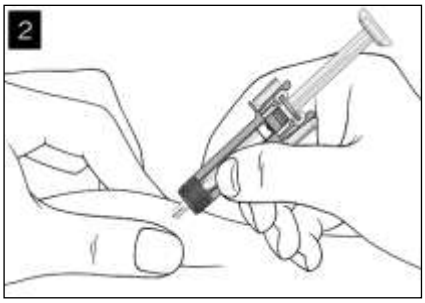
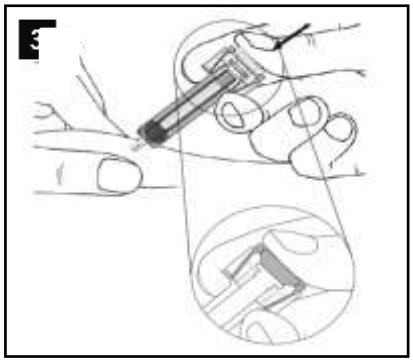
**Preparing the COSENTYX® 150 mg prefilled syringe ready for use**

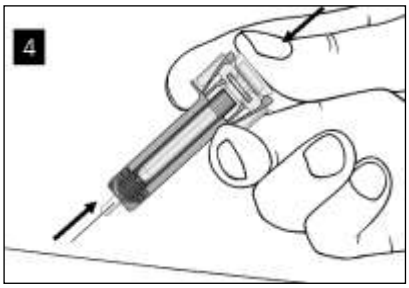
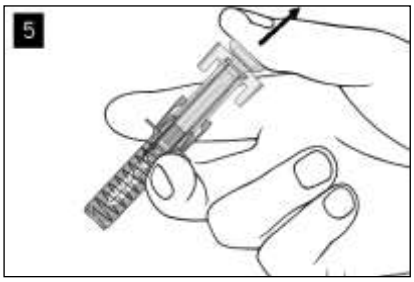
Note: For a 150 mg dose, prepare 1 pre-filled syringe and inject the content. For the 300 mg dose, prepare 2 pre-filled syringes and inject the contents of both.

1. Take the box containing the syringe out of the refrigerator and leave it **unopened** for about 15 to 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.
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

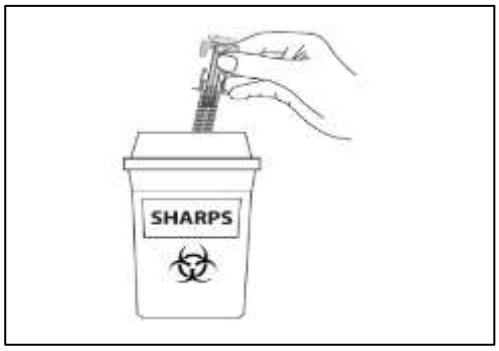
particles, is cloudy or is distinctly brown. DO NOT USE if the syringe is broken. In all these cases, return the entire product pack to the pharmacy.

**HOW TO USE THE COSENTYX® 150 mg PRE-FILLED SYRINGE**

| | |
|---|---|
|   | Carefully remove the needle cap from the syringe. 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 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.<br>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.

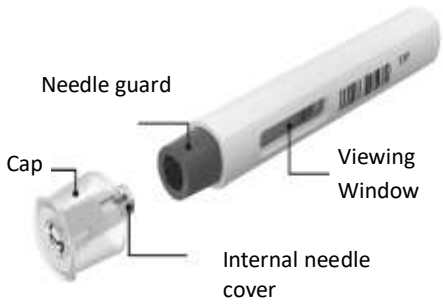
**INSTRUCTIONS FOR USE OF COSENTYX® 300 MG UNOREADY SOLUTION FOR INJECTION IN PRE-FILLED PEN**

**Read ALL the way through these instructions before injecting.**

These instructions are to help you to inject correctly using the COSENTYX® UNOREADY pen.

It is important not to try to inject yourself until you have been trained by your doctor, nurse or pharmacist.

**Your COSENTYX® UNOREADY pen 300mg:**




COSENTYX® UNOREADY pen is shown above with the cap removed. **Do not** remove the cap until you are ready to inject.

**Do not use** the COSENTYX® UNOREADY pen if the seal on the outer carton is broken.

Keep the COSENTYX® UNOREADY pen in the sealed outer carton until you are ready to use it to protect it from light.

Store your COSENTYX® UNOREADY pen in a refrigerator between 2 °C and 8 °C and out of the reach of children.

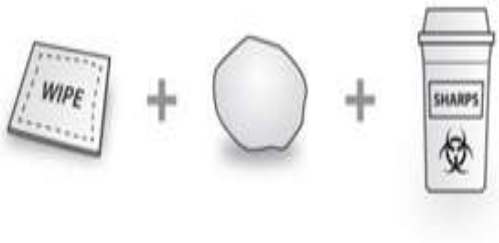
Do not **freeze** the COSENTYX® UNOREADY pen.

Do not **shake** the COSENTYX® UNOREADY pen.

Do not use the COSENTYX® UNOREADY pen if it has been **dropped** with the cap removed.

The needle is covered by the needle guard and the needle will not be seen. Do not touch or push the needle guard because you could get a needle stick.

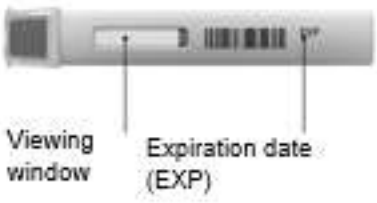
**What you need for your injection:**

| | |
|---|---|
| <br> | What you need for your injection:<br><br>Included in the carton:<br><br>• A new, unused COSENTYX® UNOREADY pen<br><br>Not included in the carton:<br><br>• Alcohol swab<br>• Cotton ball or gauze<br>• Sharps disposal container<br><br>See “How should I dispose of used COSENTYX® UNOREADY pens?” at the end of this Instructions for Use. |

**Before your injection:**

For a more comfortable injection, take the COSENTYX® UNOREADY pen out of the refrigerator **30 to 45 minutes before injecting** to allow it to reach room temperature.

| | |
|---|---|
| | **1. Important safety checks before you inject:**<br>*For the “viewing window”:*<br>The liquid should be clear. Its colour may vary from colourless |




to slightly yellow.

Do not use if the liquid contains visible particles, is cloudy or is distinctly brown. You may see air bubbles, which is normal.

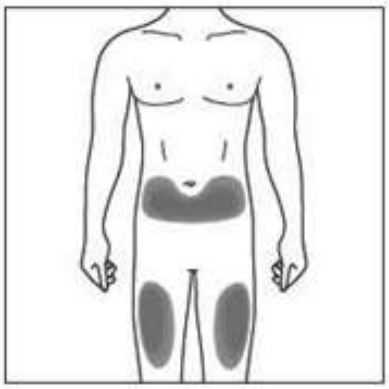
*For the "Expiration date":*

Look at the expiration date (EXP) on your COSENTYX® pen.

Do not use the pen if the expiration date has passed.

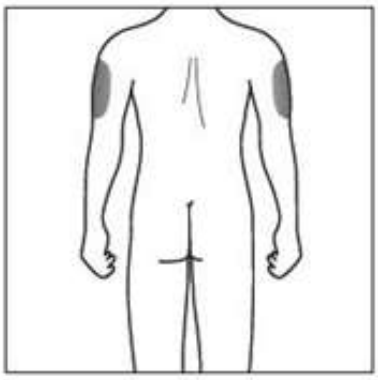
Check that your pen contains the correct medicine and dosage.

Contact your pharmacist if the pen fails any of these checks.



**2a. Choose your injection site:**

- The recommended site is the front of the thighs. You may also use the lower abdomen, but **not** the area 2 inches (5 cm) 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.

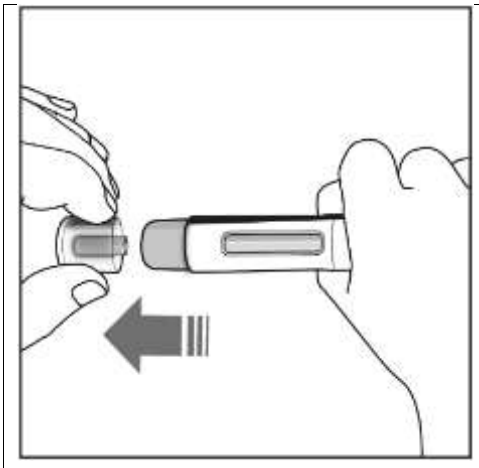


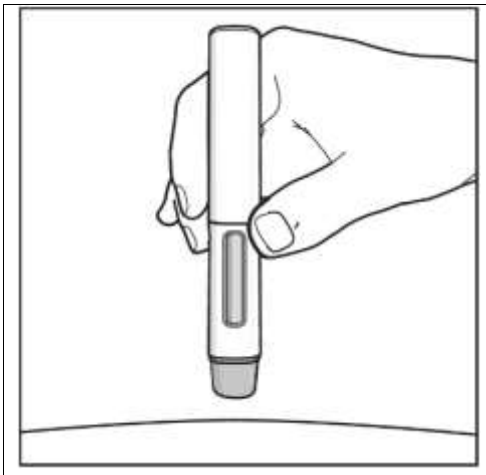
**2b. Caregivers and healthcare professionals only:**

- If a caregiver or healthcare professional is giving you your injection, they may also inject into your outer upper arm.

| | |
|---|---|
|  | **3. Cleaning your injection site:**<br>• Wash your hands with soap and hot water.<br>• Using a circular motion, clean the injection site with the alcohol swab. Leave it to dry before injecting.<br>• Do not touch the cleaned area again before injecting. |

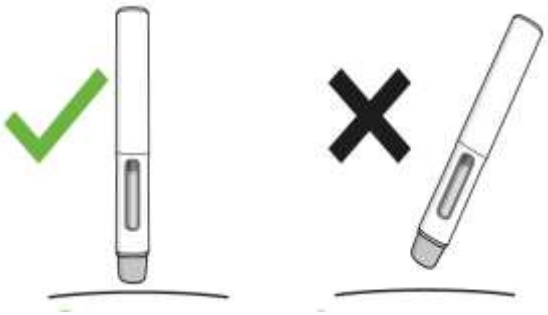
**Your injection:**

| | |
|---|---|
|  | **4. Removing the cap:**<br>• Only remove the cap when you are ready to use the pen.<br>• Pull the cap straight off in the direction of the arrow that is shown in the figure on left.<br>• Once removed, throw away the cap. Do not try to re attach the cap as you may bend the needle.<br>• Use the pen within 5 minutes of removing the cap. |



**5. Holding your COSENTYX® UNOREADY pen:**

- Hold the pen at 90 degrees to the cleaned injection site.



**Correct** **Incorrect**



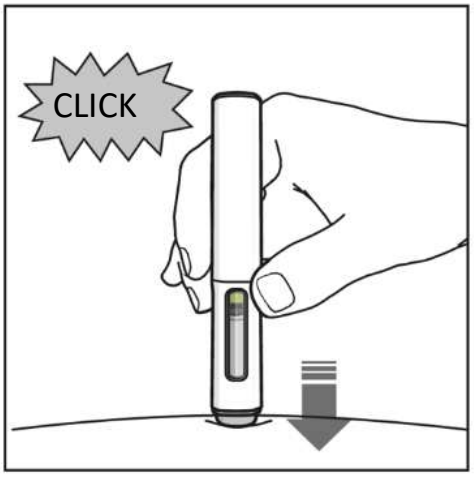
**YOU MUST READ THIS BEFORE INJECTING.**

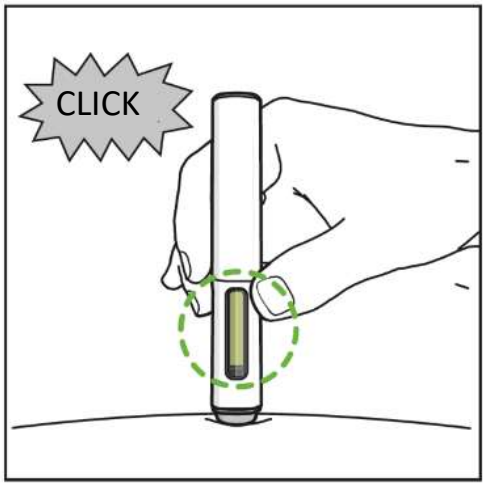
During the injection you will hear 2 clicks.

The 1st click indicates that the injection has started.

Several seconds later a 2nd click will indicate that the injection is almost finished.

You must keep holding the pen firmly against your skin until you see a green indicator with a grey tip fill the window and stop moving.



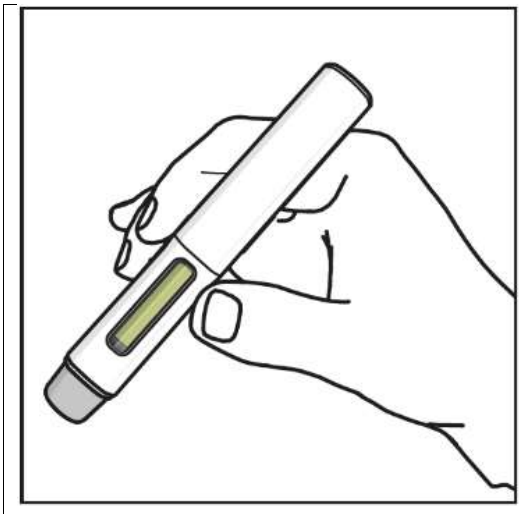
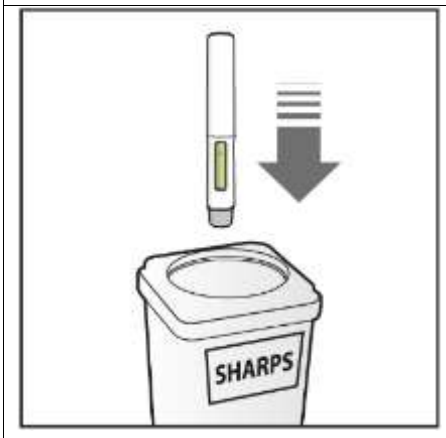

**6. Starting your injection:**

- Press the pen firmly against the skin to start the injection.
- The **1st click** indicates the injection has started.
- **Keep holding** the pen firmly against your skin.
- The **green indicator with the grey tip** shows the progress of the injection.

**7. Completing your injection:**

- Listen for the **2nd click.** This indicates the injection is **almost** complete**.**
- Check the **green indicator with the grey tip** has filled the window and has stopped moving.
- The pen can now be removed.

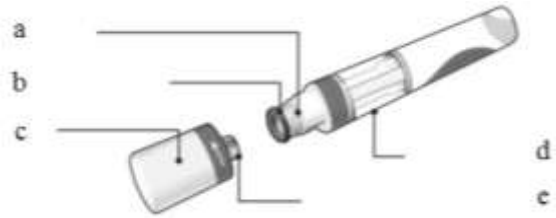
**After your injection:**

| | |
|---|---|
|  | **8. Check the green indicator fills the window:**<br>• This means the medicine has been delivered. Contact your doctor or pharmacist if the green indicator is not visible.<br>• 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. |
|  | **9. Disposing of your COSENTYX® UNOREADY pen:**<br>• Dispose of the used pen in a sharps disposal container (i.e. a puncture-resistant closable container, or similar).<br>• Never try to reuse your pen. |

**HOW TO USE THE COSENTYX® 150 mg/mL SENOREADY SOLUTION FOR INJECTION SENSOREADY IN PRE-FILLED PEN**

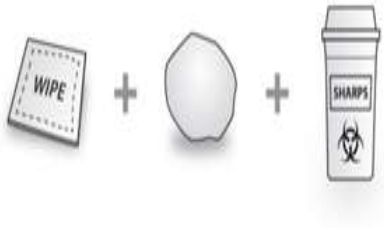
| | |
|---|---|
|  | **YOU MUST READ THIS BEFORE INJECTING.**<br>These instructions are to help you to inject correctly using the COSENTYX® 150 mg/mL solution for injection SensoReady pen.<br>It is important not to try to inject yourself or person in your care until you have been trained by your doctor, nurse or pharmacist. |

**Your COSENTYX® SensoReady pen:**

| | |
|---|---|
| <br>a. Needle<br>b. Needle guard<br>c. Cap<br>d. Inspection window<br>e. Internal needle cover<br><br>COSENTYX® SensoReady pen shown with the cap removed. Do not remove the cap until you are ready to inject. | Store your boxed COSENTYX® SensoReady pen in a **refrigerator** between 2 °C and 8 °C and **out of the reach of children**.<br>Do not **freeze** the COSENTYX® SensoReady pen.<br>Do not **shake** the COSENTYX® SensoReady pen.<br>Do not use the COSENTYX® SensoReady pen if it has been **dropped** with the cap removed.<br><br>For a more comfortable injection, take the COSENTYX® SensoReady pen out of the |

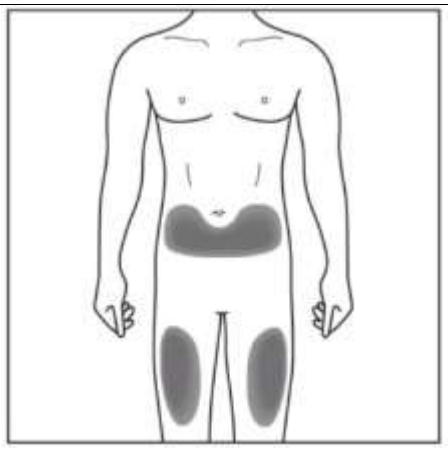
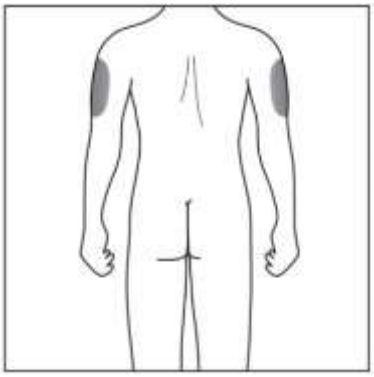
| | |
|---|---|
| | refrigerator **15 to 30 minutes before injecting** to allow it to reach room temperature. |

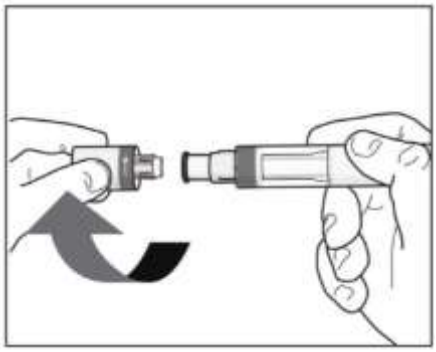
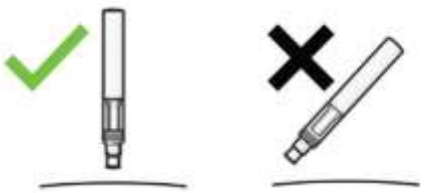
**What you need for your injection**

| | | |
|---|---|---|
| Included in the carton:<br>A new and unused COSENTYX® SensoReady pen. 1 pen is needed for a 150 mg dose and 2 pens are needed for a 300 mg dose.<br> | Not Included in the carton:<br>• Alcohol swab.<br>• Cotton ball or gauze.<br>• Sharps disposal container. |  |

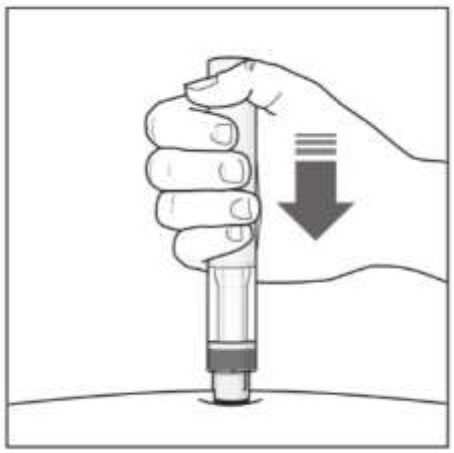
**Before your injection**

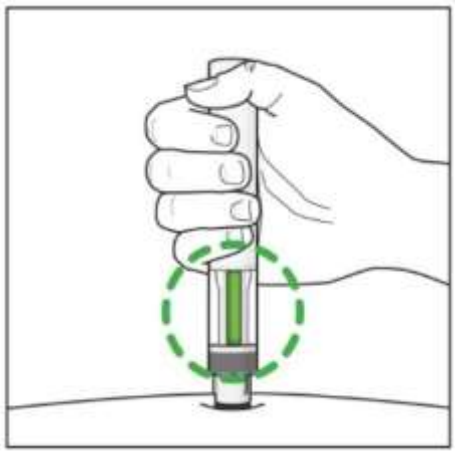
| | |
|---|---|
|  | **1. Important safety checks before you inject:**<br>• The liquid should be clear. Its colour may vary from colourless to slightly yellow.<br>• Do not use if the liquid contains easily visible particles, is cloudy or is distinctly brown. You may see a small air bubble, which is normal.<br>• Do not use the pen if the expiry date has passed.<br>• Do not use if the safety seal has been broken. |

| | |
|---|---|
| | • Contact your pharmacist if the pen fails any of these checks. |
|  | **2a. Choose your injection site:**<br>• The recommended site is the front of the thighs. You may also use the lower abdomen, but **not** the area 2 inches (~ 50 mm) around the navel (belly button).<br>• Choose a different site each time you give yourself an injection.<br>• Do not inject into areas where the skin is tender, bruised, red, scaly or hard. Avoid areas with scars or stretch marks. |
|  | **2b. Caregivers and Healthcare Professionals Only:**<br>• If a **caregiver** or **healthcare professional** is giving you your injection, they may also inject into your outer upper arm. |

<table>
<tr><td></td><td>3. Cleaning your injection site:<br>• Wash your hands with soap and hot water.<br>• Using a circular motion, clean the injection site with the alcohol swab. Leave it to dry before injecting.<br>• Do not touch the cleaned area again before injecting</td></tr>
<tr><td colspan="2">Your injection</td></tr>
<tr><td></td><td>4. Removing the cap:<br>• Only remove the cap when you are ready to use the pen.<br>• Twist off the cap in the direction of the arrows.<br>• Once removed, throw away the cap. Do not try to re-attach the cap.<br>• Use the pen within 5 minutes of removing the cap.</td></tr>
<tr><td></td><td>5. Holding your pen:<br>• Hold the pen at 90 degrees to the cleaned injection site.<br><br>Correct Incorrect</td></tr>
</table>

| | |
|---|---|
|  | **YOU MUST READ THIS BEFORE INJECTING.**<br>During the injection you will hear **2 loud clicks**.<br><br>The **1st click** indicates that the injection has started. Several seconds later a **2nd click** will indicate that the injection is **almost** finished.<br><br>You must keep holding the pen firmly against your skin until you see a **green indicator** fill the window and stop moving. |

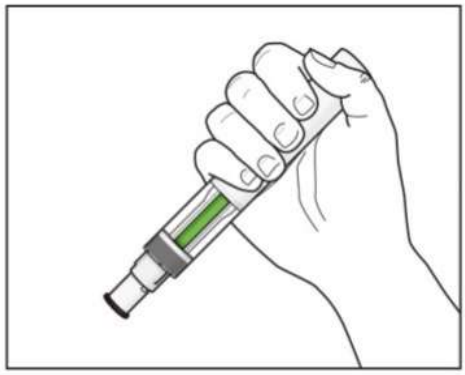
| | |
|---|---|
|  | **6. Starting your Injection:**<br>• Press the pen firmly against the skin to start the injection.<br>• **The 1st click** indicates the injection has started.<br>• **Keep holding** the pen firmly against your skin.<br>• The **green indicator** shows the progress of the injection. |



**7. Completing your injection:**

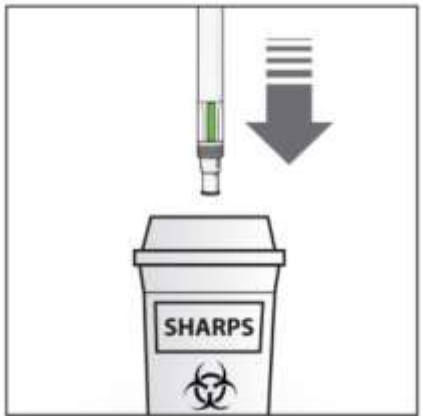
- Listen for the **2nd click**. This indicates the injection is **almost** complete.
- Check the **green indicator** fills the window and has stopped moving.
- The pen can now be removed.

**After your injection**



**8. Check the green indicator fills the window:**

- This means the medicine has been delivered. Contact your doctor if the green indicator is not visible.
- 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.

| | |
|---|---|
|  | **9. Disposing of your COSENTYX® SensoReady pen:**<br>• Dispose of the used pen in a sharps disposal container (i.e. a puncture-resistant closable container, or similar).<br>• Never try to reuse your pen. |

**4. Possible side effects**

COSENTYX® can have side effects.

Not all side effects reported for COSENTYX® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking COSENTYX®, please consult your health care provider for advice.

**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)
- Itchy rash, dry skin, dry patches, inflamed skin, coin-shaped spots on the skin [dermatitis (including 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)
- athlete's foot (tinea pedis)
- infection of the external ear (otitis externa)
- discharge from the eye with itching, redness and swelling (conjunctivitis)
- itchy rash (urticaria)
- lower respiratory tract infections
- nausea, abdominal cramps and pain, diarrhoea, vomiting, weight loss or blood in the stool (signs of bowel problems) and fever (symptoms of inflammatory bowel disease)
- Small, itchy blisters on the palms of hands, soles of feet and edges of the fingers and toes (dyshidrotic eczema).

**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)

**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)
- Severe inflammation of the entire skin surface (dermatitis exfoliative)

- Inflammation of small blood vessels, which can lead to a skin rash with small red or purple bumps (hypersensitivity vasculitis)
- Swelling of the face, lips, tongue or throat (angioedema)

**Reporting of side effects**

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (wh-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of COSENTYX®.

**5. How to store COSENTYX®**

Store all medicines out of reach of children.

**SOLUTION FOR INJECTION IN A PRE-FILLED SYRINGE OR PRE-FILLED PEN**

- Store COSENTYX® pre-filled syringe or SensoReady or UNOREADY pens sealed in its box to protect from light.
- Store in the refrigerator between 2 °C and 8 °C. DO NOT FREEZE.
- Do not shake.
- When necessary, COSENTYX® can be left out of the refrigerator for up to 4 days at room temperature, not above 30 °C.

Do not use COSENTYX® pre-filled syringe or SensoReady or UNOREADY pens:

- After the expiration date shown on the outer box or the label on the syringe or pen.
- If the liquid contains easily visible particles, is cloudy or is distinctly brown.

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

**SOLUTION FOR INJECTION IN A PRE-FILLED SYRINGE OR PRE-FILLED PEN**

- The active substance is secukinumab. Each pre-filled syringe/pen contains either 150 mg or 300 mg secukinumab. The SensoReady pen contains 150 mg and the UNOREADY pen contains 300 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® 300 mg/2 mL, 150 mg/mL Solution for Injection:**

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

COSENTYX® is available in unit packs containing 1 or 2 pre-filled syringe(s) or pen(s).

Not all pack sizes may be marketed.

### Holder of Certificate of Registration

Novartis South Africa (Pty) Ltd.

Magwa Crescent West

Waterfall City, Jukskei View

Johannesburg, 2090

South Africa

(011) 347 6600

**This leaflet was last revised in**

30 April 2026

**Registration numbers**

**COSENTYX® 300 mg/2 mL Solution for Injection:** 56/30.1/0242

**COSENTYX® 150 mg/mL Solution for Injection:** 49/30.1/0233

| Namibia | |
|---|---|
| COSENTYX® 150 mg/ml Solution for Injection: 19/30.1/0059 | NS2 |
| Manufacturers:<br>*Novartis Pharma Stein AG Schaffhauserstrasse 4332 Stein, Switzerland*<br>*Novartis Pharmaceutical Manufacturing GmbH, Biochemiestraße 10 6336 Langkampfen, Austria* | |

*VAR_20260803_78949*