

PART III: CONSUMER INFORMATION**PrCOSENTYX®
(Secukinumab)**

This leaflet is part III of a three-part "Product Monograph" published when COSENTYX was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about COSENTYX. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

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

- Plaque psoriasis
- Psoriatic arthritis
- Ankylosing spondylitis

Plaque psoriasis

COSENTYX is used to treat a skin condition called 'plaque psoriasis'. Plaque psoriasis causes inflammation affecting the skin. COSENTYX will reduce the inflammation and other symptoms of the disease.

COSENTYX is used in adults with moderate to severe plaque psoriasis.

Psoriasis can cause raised, thick, red and scaly patches ("psoriatic lesions") that can appear anywhere on your body.

Psoriatic arthritis

COSENTYX is used in adults with active psoriatic arthritis and can be used alone or with another medicine called methotrexate. You may first be given other medicines for this disease. If you do not respond well enough to these medicines, you will be given COSENTYX.

The condition is an inflammatory disease of the joints, often accompanied by psoriasis.

Ankylosing spondylitis

COSENTYX is used to treat a condition called 'ankylosing spondylitis'. The condition is an inflammatory disease primarily affecting the spine, which causes inflammation of the spinal joints.

COSENTYX is used in adults with active ankylosing spondylitis.

You may first be given other medicines for this disease. If you do not respond well enough to these medicines, you will be given COSENTYX.

What it does:

COSENTYX contains the active substance secukinumab. Secukinumab is a fully-human monoclonal antibody. Monoclonal antibodies are proteins that recognize and bind specifically to certain proteins in the body.

COSENTYX 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 ankylosing spondylitis. COSENTYX helps reduce the signs and symptoms of psoriasis such as pain, itching, and scaly patches. In addition, COSENTYX helps reduce the signs and symptoms of psoriatic arthritis and ankylosing spondylitis.

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

When it should not be used:**Do not use COSENTYX:**

- **If you had a severe allergic reaction** to secukinumab or any of the other ingredients of COSENTYX.
- If you think you may be allergic, ask your doctor for advice before using COSENTYX.
- Do not take COSENTYX if you have any signs of infection or an active tuberculosis infection unless you are instructed to by your healthcare provider.

What the medicinal ingredient is:

Secukinumab

What the important nonmedicinal ingredients are:

Solution for injection: Trehalose dehydrate, L-histidine/histidine hydrochloride monohydrate, L-methionine, polysorbate 80, water for injection

Powder for solution for injection*: Sucrose, L-histidine, L-histidine hydrochloride monohydrate, polysorbate 80, water for injection

What dosage forms it comes in:

Solution for injection in a pre-filled syringe (150 mg/mL) or pre-filled SensoReady® pen (150 mg/mL) or single-use vial (lyophilized powder for solution for injection) (150 mg)*.

*single-use vial not available in Canada

WARNINGS AND PRECAUTIONS

COSENTYX is a medicine that affects your immune system.

COSENTYX may increase your risk of having serious side effects such as infections.

BEFORE you use COSENTYX talk to your doctor or pharmacist if:

- you currently have an infection or if you have long-term or repeated infections.
- you have tuberculosis. Your doctor should check you for tuberculosis before starting treatment.
- you ever had an allergic reaction to latex. The needle cap on the COSENTYX SensoReady pen and pre-filled syringe contains a derivative of latex.
- you have Crohn's disease or ulcerative colitis.
- you had a recent vaccination or if you will receive a vaccination during treatment with COSENTYX.

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

You have worsening symptoms or develop new symptoms of stomach pain or diarrhea.

Signs or symptoms of a potentially serious infection. These may include:

- fever, flu-like symptoms, muscle aches, 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 water

Signs or symptoms of an allergic reaction. These may include:

- chest tightness, difficulty breathing or swallowing
- low blood pressure, which can cause dizziness or light-headedness
- swelling of the face, lips, mouth or throat

Do not use COSENTYX if you have any signs of infections or an allergic reaction unless you are instructed to by your healthcare provider.

Children and adolescents (below the age of 18 years)

COSENTYX is not recommended for children and adolescents (under 18 years of age) because it has not been studied in this age group.

Pregnancy and breast-feeding

Talk to your doctor before using COSENTYX:

- If you are pregnant, think that you may be pregnant or are planning to have a baby.
- COSENTYX is not recommended during pregnancy unless the benefits clearly outweigh the potential risks.
- If you are breast-feeding or plan to breast-feed.
- It is not known if COSENTYX passes into your breast milk.

INTERACTIONS WITH THIS MEDICATION

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 going to have a vaccination. You should not receive certain types of vaccines (live vaccines) while using COSENTYX.

PROPER USE OF THIS MEDICATION

Your healthcare provider will prescribe the dose of COSENTYX that is right for you.

- If your prescribed dose of COSENTYX is **150 mg**, administer **1 injection** of COSENTYX for each dose.
- If your prescribed dose of COSENTYX is **300 mg**, administer **2 injections** for each dose.

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 administered via injection under your skin ('subcutaneously').

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.

Usual dose:

Your doctor will decide how much COSENTYX you need.

Plaque psoriasis

The recommended dose is 300 mg by subcutaneous injection with initial dosing at weeks 0, 1, 2, 3, and 4 followed by monthly maintenance dosing. Each 300 mg dose is given as two subcutaneous injections of 150 mg.

Psoriatic arthritis

The recommended dose is 150 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3, and 4 followed by monthly maintenance dosing.

For psoriatic arthritis patients with coexistent moderate to severe plaque psoriasis, use the dosing and administration recommendations for plaque psoriasis.

For patients who did not respond well to medicines called tumor necrosis factor (TNF) blockers and continues to have active psoriatic arthritis, the 300 mg dose may be given.

Ankylosing spondylitis

The recommended dose is 150 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3, and 4 followed by monthly maintenance dosing.

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

Overdose:

If you accidentally injected more COSENTYX or sooner than according to your doctor's prescription, inform your doctor.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

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.

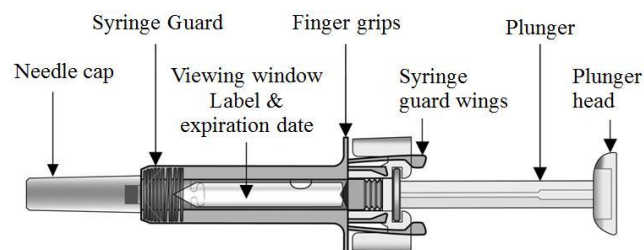
COSENTYX solution for injection is a clear liquid. Its color may vary from colorless to slightly yellow. COSENTYX is available in packs containing 1 or 2 pre-filled syringe(s) or SensoReady pens.

Instructions for use of the COSENTYX 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 1 or 2

COSENTYX prefilled syringe(s) individually sealed in a plastic blister.

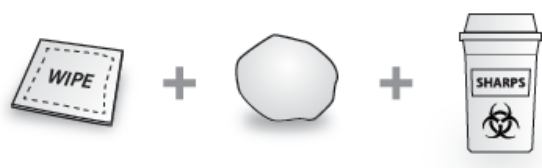
Your COSENTYX pre-filled syringe



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 medications and individuals that assist self-injecting patients from accidental needle sticks.

What you additionally need for your injection:

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



Important safety information

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

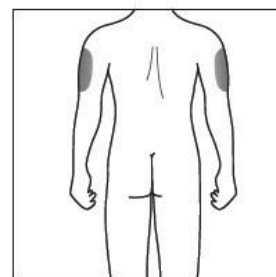
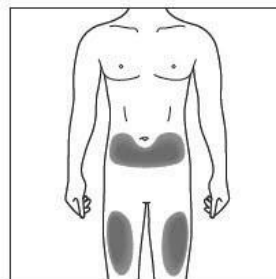
1. The needle cap of the syringe may contain dry rubber (latex), which should not be handled by persons sensitive to this substance.
2. Do not open the sealed outer box until you are ready to use the COSENTYX pre-filled syringe.
3. Do not use the COSENTYX pre-filled syringe if either the seal on the outer box or the seal of the blister are broken, as it may not be safe for you to use.
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 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 (15 to 30 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.

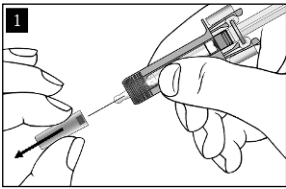
- The recommended site is the front of your thighs. You may also use the lower abdomen, but **not** the area 2 inches around the navel (belly button). If a caregiver is giving you the injection, the outer upper arms may also be used.
- Choose a different site each time you give yourself an injection.
- 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 pre-filled syringe ready for use

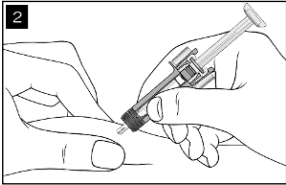
1. Take the box containing the COSENTYX pre-filled syringe out of the refrigerator and leave it **unopened** for about 15 to 30 minutes so that it reaches room temperature.
2. When you are ready to use the COSENTYX pre-filled syringe, wash your hands thoroughly with soap and water.
3. Clean the injection site with an alcohol swab.
4. Remove the COSENTYX pre-filled syringe from the outer box and take it out of the blister.
5. Inspect the COSENTYX pre-filled syringe. The liquid should be clear. Its color may vary from colorless 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 pre-filled syringe

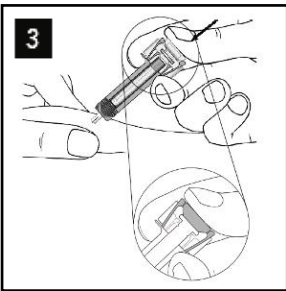
syringes **must never** be re-used.



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.

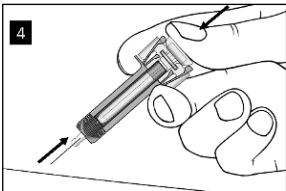


Gently pinch the skin at the injection site and insert the needle as shown. Push the needle all the way in to ensure that the medication can be fully administered.

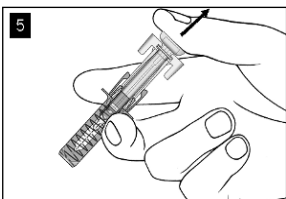


Holding the COSENTYX pre-filled syringe as shown, **slowly** depress the plunger **as far as it will go** so that the plunger head is completely between the syringe guard wings.

Keep the plunger pressed fully down while you hold the syringe in place for 5 seconds.



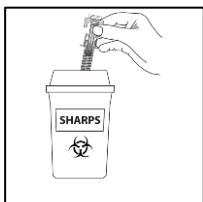
Keep the plunger fully depressed while you carefully lift the needle straight out from the injection site.



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



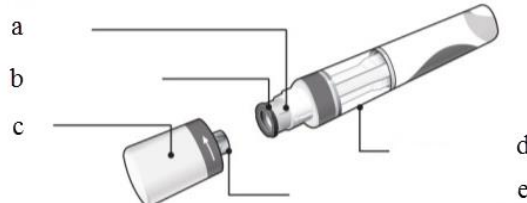
Dispose of the used COSENTYX pre-filled syringe in a sharps container (closable, puncture resistant container). For the safety and health of you and others, needles and used

Instructions for use of COSENTYX SensoReady pen

Read ALL the way through these instructions before injecting.

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

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



- a. Needle
- b. Needle guard
- c. Cap
- d. Inspection window
- e. Internal needle cover

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**.

Do not **freeze** the COSENTYX SensoReady pen.

Do not **shake** the COSENTYX SensoReady pen.

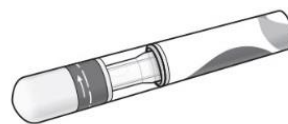
Do not use the COSENTYX SensoReady pen if it has been **dropped** with the cap removed.

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:

- A new and unused COSENTYX SensoReady pen.

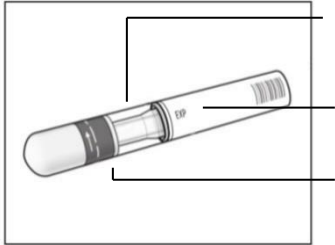


Not Included in the carton:

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

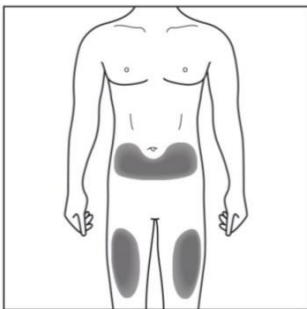


Before your injection



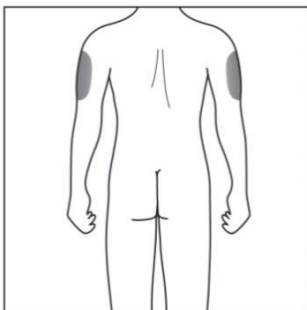
1/ Important safety checks before you inject:

- The liquid should be clear. Its color may vary from colorless to slightly yellow.
- **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.
- **Do not use** your COSENTYX SensoReady pen if the **expiration date** has passed.
- **Do not use** if the **safety seal** has been broken.
- Contact your pharmacist if the COSENTYX SensoReady pen fails any of these checks.



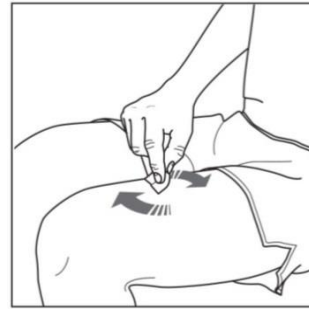
2a/ Choose your injection site:

- The recommended site is the front of the thighs. You may also use the lower abdomen, but not the area 2 inches 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:

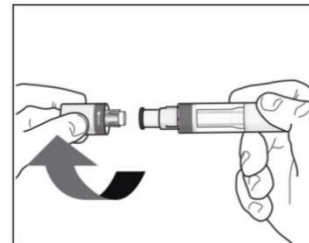
If a **caregiver** or **healthcare professional** is giving you your injection, they may also inject into your outer upper arm.



3/ Cleaning your injection site:

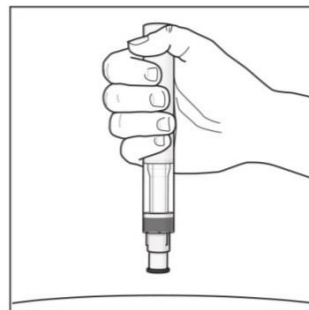
- Wash your hands with hot soapy water.
- Using a circular motion, clean the injection site with the alcohol swab. Leave it to dry before injecting.
- Do not touch the cleaned area again before injecting.

Your injection



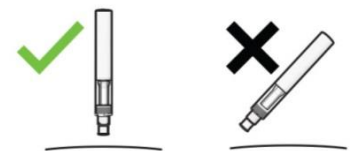
4/ Removing the cap:

- Only remove the cap when you are ready to use the COSENTYX SensoReady pen.
- Twist off the cap in the direction of the arrows.
- Once removed, throw away the cap. **Do not try to re-attach the cap.**
- Use the COSENTYX SensoReady pen within 5 minutes of removing the cap.



5/ Holding your COSENTYX SensoReady pen:

- Hold the COSENTYX SensoReady pen at 90° to the cleaned injection site.



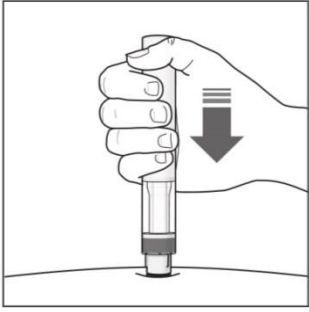
Correct Incorrect

YOU MUST READ THIS BEFORE INJECTING.

During the injection you will hear **2 loud clicks**.

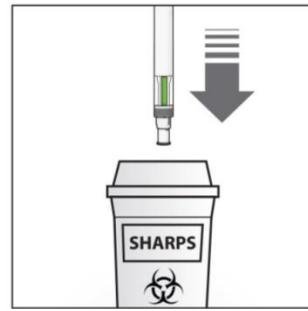
The **1st click** indicates that the injection has started. Several seconds later a **2nd click** will indicate that the injection is **almost finished**.

You must keep holding the COSENTYX SensoReady pen firmly against your skin until you see a **green indicator** fill the window and stop moving.



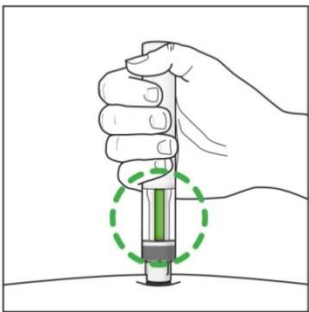
6/ Starting your Injection:

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



9/ Disposing of your COSENTYX SensoReady pen:

- Dispose of the used COSENTYX SensoReady pen in a sharps disposal container (i.e. a puncture-resistant closable container, or similar).
- Never try to reuse your COSENTYX SensoReady pen.



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 COSENTYX SensoReady pen can now be removed.

Instructions for use of COSENTYX powder for solution for injection*

*single-use vial not available in Canada

The following information is intended for medical or healthcare professionals only.

Store the vial of 150 mg powder for solution for injection of COSENTYX in the refrigerator between 2°C to 8°C.

The single-use vial contains 150 mg of COSENTYX for reconstitution with sterile water for injection (SWFI). Do not use the vial after the expiry date shown on the outer box or vial. If it has expired, return the entire pack to the pharmacy.

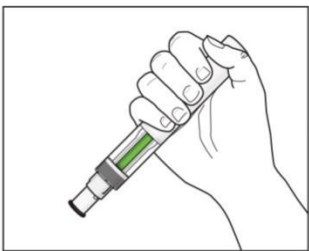
The preparation of the solution for subcutaneous injection shall be done without interruption ensuring that aseptic technique is used. The preparation time from piercing the stopper until end of reconstitution on average takes 20 minutes and should not exceed 90 minutes.

To prepare COSENTYX 150 mg powder for solution for injection please adhere to the following instructions:

Instructions for reconstitution of COSENTYX 150 mg powder for solution for injection:

1. Bring the vial of COSENTYX 150 mg powder for solution for injection to room temperature and ensure sterile water for injection (SWFI) is at room temperature.
2. Withdraw slightly more than 1.0 mL sterile water for injection (SWFI) into a 1 mL graduated disposable syringe and adjust to 1.0 mL.
3. Remove the plastic cap from the vial.
4. Insert the syringe needle into the vial containing the lyophilized cake of COSENTYX through the center of the rubber stopper and reconstitute the cake by slowly injecting 1.0 mL of SWFI into the vial. The stream of SWFI should be directed onto the lyophilized cake.

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.



- Tilt the vial to an angle of approx. 45° and gently rotate between the fingertips for approx. 1 minute. Do not shake or invert the vial.



- Keep the vial standing at room temperature for a minimum of 10 minutes to allow for dissolution. Note that foaming of the solution may occur.
- Tilt the vial to an angle of approx. 45° and gently rotate between the fingertips for approx. 1 minute. Do not shake or invert the vial.



- Allow the vial to stand undisturbed at room temperature for approximately 5 minutes. The resulting solution should be clear. Its color may vary from colorless to slightly yellow. Do not use if the lyophilized powder has not fully dissolved or if the liquid contains easily visible particles, is cloudy or is distinctly brown.
- Prepare the required number of vials (2 vials for the 300 mg dose).

After preparation, the solution for subcutaneous injection can be used immediately or can be stored at 2°C to 8°C for up to 24 hours. Do not freeze. After storage at 2°C to 8°C, the solution should be allowed to come to room temperature for approximately 20 minutes before administration. The solution should be administered within 1 hour after removal from the 2°C to 8°C storage.

Instructions for administration of COSENTYX solution

- Tilt the vial to an angle of approximately 45° and position the needle tip at the very bottom of the solution in the vial when drawing the solution into the syringe. **DO NOT** invert the vial.



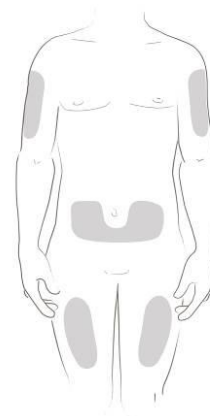
- Carefully withdraw slightly more than 1.0 mL of the solution for subcutaneous injection from the vial into a 1 mL graduated disposable syringe using a suitable needle (e.g. 21G x 2”). This needle will only be used for withdrawing COSENTYX into the disposable syringe. Prepare the required number of syringes (2 syringes for the 300 mg dose).
- With the needle pointing upward, gently tap the syringe to move any air bubbles to the top.



- Replace the attached needle with a 27G x ½” needle.



- Expel the air bubbles and advance the plunger to the 1.0 mL mark.
- Clean the injection site with an alcohol swab.
- Inject the COSENTYX solution subcutaneously into the front of thighs, lower abdomen (but **not** the area 2 inches around the navel (belly button) or outer upper arms. Choose a different site each time an injection is administered. Do not inject into areas where the skin is tender, bruised, red, scaly or hard. Avoid areas with scars or stretch marks.



- Any remaining solution in the vial must not be used and should be discarded in accordance with local requirements. Vials are for single use only. 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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

As with all medicines, patients treated with COSENTYX may experience side effects.

STOP using COSENTYX and seek medical help immediately if you experience any of the following, which are signs of an allergic reaction:

- difficulty breathing or swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps

Possible side effects

Side effects include the following listed below. Most of the side effects are mild to moderate. If these side effects become severe, please tell your doctor, pharmacist or healthcare provider.

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

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

Some side effects are common (*These side effects may affect up to 1 in every 10 people*)

- Cold sores (oral herpes)
- Diarrhea
- Itchy rash (urticaria)
- Runny nose (rhinorrhea)

Some side effects are uncommon (*These side effects may affect up to 1 in every 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)
- Discharge from the eye with itching, redness and swelling (conjunctivitis)

Not known (*frequency cannot be estimated from available data*)

- Fungal infections of the skin and mucous membranes (thrush)

If you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

- Store COSENTYX pre-filled syringe or SensoReady pen sealed in its box to protect from light.
- Store in the refrigerator between 2°C and 8°C. DO NOT FREEZE.
- Do not shake.
- If necessary, the pre-filled syringe and the SensoReady pen may be stored unrefrigerated for a single period of up to 4 days at room temperature, not above 30°C. Discard the pre-filled syringe or SensoReady pen after 4 days if left unrefrigerated.

Do not use COSENTYX pre-filled syringe or SensoReady pen:

- After the expiration date shown on the outer box or the label on the syringe or the SensoReady pen.
- If the liquid contains easily visible particles, is cloudy or is distinctly brown.
- Any unused product or waste material should be disposed of in accordance with local requirements. Ask your pharmacist how to dispose of medicines you no longer use.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Rare	Serious allergic reactions		√	√

This is not a complete list of side effects. For any unexpected effects while taking COSENTYX, contact your doctor or pharmacist.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: <http://www.novartis.ca> or by contacting the sponsor, Novartis Pharmaceuticals Canada Inc., at: 1-800-363-8883

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HOW TO STORE IT

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

COSENTYX and SensoReady are registered trademarks.