

MEDICATION GUIDE
COSENTYX® (koe-sen-tix)
(secukinumab)

injection, for subcutaneous or intravenous use

What is the most important information I should know about COSENTYX?

COSENTYX is a medicine that affects your immune system. COSENTYX may increase your risk of having serious side effects such as:

Infections. COSENTYX may lower the ability of your immune system to fight infections and may increase your risk of infections. Some people have died from these infections.

- Your healthcare provider should check you for tuberculosis (TB) before starting treatment with COSENTYX.
- If your healthcare provider feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment with COSENTYX and during treatment with COSENTYX.
- Your healthcare provider should watch you closely for signs and symptoms of TB during treatment with COSENTYX. **Do not use COSENTYX if you have an active TB infection.**

Before starting COSENTYX, tell your healthcare provider if you:

- are being treated for an infection
- have an infection that does not go away or that keeps coming back
- have TB or have been in close contact with someone with TB
- think you have an infection or have symptoms of an infection such as:
 - fever, sweats, or chills
 - muscle aches
 - cough
 - shortness of breath
 - blood in your phlegm
 - weight loss
 - warm, red, or painful skin or sores on your body
 - diarrhea or stomach pain
 - burning when you urinate or urinate more often than normal

After starting COSENTYX, call your healthcare provider right away if you have any of the signs of infection listed above. Do not use COSENTYX if you have any signs of infection unless you are instructed to by your healthcare provider.

See “**What are the possible side effects of COSENTYX?**” for more information about side effects.

What is COSENTYX?

COSENTYX is a prescription medicine used to treat:

- people 6 years of age and older with moderate to severe plaque psoriasis (PsO) that involves large areas or many areas of the body, and who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet or UV light alone or with systemic therapy)
- people 2 years of age and older with active psoriatic arthritis (PsA)
- adults with active ankylosing spondylitis (AS)
- adults with active non-radiographic axial spondyloarthritis (nr-axSpA) and objective signs of inflammation
- people 4 years of age and older with active enthesitis-related arthritis (ERA)
- adults with moderate to severe hidradenitis suppurativa (HS)

It is not known if COSENTYX is safe and effective in children:

- under 6 years of age with PsO
- under 2 years of age and weighing less than 33 pounds (15 kg) with active PsA
- under 4 years of age and weighing less than 33 pounds (15 kg) with active ERA
- with HS

Do not use COSENTYX if you:

- have had a severe allergic reaction to secukinumab or any of the other ingredients in COSENTYX. See the end of this Medication Guide for a complete list of ingredients in COSENTYX.

Before using COSENTYX, tell your healthcare provider about all of your medical conditions, including if you:

- have any of the conditions or symptoms listed in the section “**What is the most important information I should know about COSENTYX?**”
- have inflammatory bowel disease (Crohn’s disease or ulcerative colitis).
- are allergic to latex. The needle cap on the COSENTYX Sensoready pen, and 150 mg/mL and 75 mg/0.5 mL prefilled syringes contains latex.
- have recently received or are scheduled to receive an immunization (vaccine). People who take COSENTYX **should not** receive live vaccines. Children should be brought up to date with all vaccines before starting COSENTYX.
- are pregnant or plan to become pregnant. It is not known if COSENTYX can harm your unborn baby. You and your healthcare provider should decide if you will use COSENTYX.
- are breastfeeding or plan to breastfeed. It is not known if COSENTYX passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of your medicines to show your healthcare provider and pharmacist when you get a new medicine.

How will I receive COSENTYX?**When administered subcutaneously (under your skin)**

Read the detailed “Instructions for Use” that comes with your COSENTYX for information on how to prepare and inject a dose of COSENTYX, and how to properly throw away (dispose of) used COSENTYX.

- Use COSENTYX exactly as prescribed by your healthcare provider.
- COSENTYX comes in a single-dose UnoReady pen, single-dose Sensoready pen, or single-dose prefilled syringes (300 mg/2 mL, 150 mg/mL, 75 mg/0.5 mL) that you or your caregiver may use at home to give injections.
- Your healthcare provider will decide which type of COSENTYX, and which dose is right for you.
- If your healthcare provider decides that you or a caregiver may give your injections of COSENTYX at home, you should receive training on the right way to prepare and inject COSENTYX. Do not try to inject COSENTYX yourself, until you or your caregiver has been shown how to inject COSENTYX by your healthcare provider.
- Children should not inject themselves with COSENTYX. An adult caregiver should prepare and inject COSENTYX after receiving training on the right way to prepare and inject COSENTYX.
- **Do not handle the needle cap of the COSENTYX Sensoready pen, or the 75 mg/0.5 mL or 150 mg/mL prefilled syringes if you are sensitive to latex.**
- COSENTYX is given as an injection under your skin (subcutaneous injection), in your upper legs (thighs) or stomach-area (abdomen) by you or a caregiver. A caregiver or healthcare provider may also give you an injection of COSENTYX in your upper outer arm.
- **Do not** give an injection in an area of the skin that is tender, bruised, red or hard, or in an area of skin that is affected by psoriasis.
- Each injection should be given at a different site. **Do not** use the 2-inch area around your navel (belly button).
- If you inject more COSENTYX than prescribed, call your healthcare provider or Poison Help line at 1-800-222-1222, or go to the nearest emergency room right away.

When administered intravenously (by vein)

- You will be given COSENTYX by a healthcare provider through a needle placed in a vein (infusion). It takes about 30 minutes to give you the full dose of COSENTYX.
- Your healthcare provider will tell you how often you should receive COSENTYX.
- If you miss an appointment to receive COSENTYX, make another appointment as soon as possible.

What are the possible side effects of COSENTYX?**COSENTYX may cause serious side effects, including:**

- See “**What is the most important information I should know about COSENTYX?**”
- **Serious allergic reactions.** Get emergency medical help right away if you get any of the following symptoms of a serious allergic reaction:
 - feel faint
 - trouble breathing or throat tightness
 - skin rash

- swelling of your face, eyelids, lips, mouth, tongue, or throat
- chest tightness
- hives (red, itchy bumps)

If you have a severe allergic reaction, do not give another injection of COSENTYX.

- **Inflammatory bowel disease.** New cases of inflammatory bowel disease or “flare-ups” can happen with COSENTYX and can sometimes be serious. If you have inflammatory bowel disease (ulcerative colitis or Crohn’s disease), tell your healthcare provider if you have worsening disease symptoms during treatment with COSENTYX or develop new symptoms of stomach pain or diarrhea.
- **Severe skin reactions that look like eczema** can happen during treatment with COSENTYX from days to months after your first dose and can sometimes lead to hospitalization. Your healthcare provider may temporarily stop treatment with COSENTYX if you develop severe skin reactions. Tell your healthcare provider if you have any of the following signs or symptoms:
 - redness or rash
 - itching
 - small bumps or patches
 - your skin is dry or feels like leather
 - blisters on the hands or feet that ooze or become crusty
 - skin peeling

The most common side effects of COSENTYX include:

- cold symptoms
- diarrhea
- upper respiratory tract infections

These are not all of the possible side effects of COSENTYX.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store COSENTYX?

- Store COSENTYX in a refrigerator, between 36°F to 46°F (2°C to 8°C).
- Keep COSENTYX in the original carton until ready for use to protect from light.
- **If you use COSENTYX Sensoready pen, or COSENTYX 75 mg/0.5 mL or 150 mg/mL prefilled syringe:**
 - It may be stored at room temperature, up to 86°F (30°C), for up to 4 days.
 - Write the date it was removed from and returned to the refrigerator in the space provided on the carton.
 - Throw it away if it has been stored outside of the refrigerator over 4 days.
 - It may be returned to the refrigerator **only 1 time** and must be stored between 36°F to 46°F (2°C to 8°C) until you use it or until it expires.
- Do not freeze COSENTYX.
- Do not shake COSENTYX.
- Throw away any expired or unused COSENTYX.

Keep COSENTYX and all medicines out of the reach of children.

General information about the safe and effective use of COSENTYX.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use COSENTYX for a condition for which it was not prescribed. Do not give COSENTYX to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about COSENTYX that is written for health professionals.

What are the ingredients in COSENTYX?

Active ingredient: secukinumab.

Inactive ingredients:

L-histidine/histidine hydrochloride monohydrate, L-methionine, polysorbate 80, trehalose dihydrate, and sterile water for injection.

Manufactured by: Novartis Pharmaceuticals Corporation, East Hanover, New Jersey 07936, U.S. License Number 1244

For more information, call 1-888-669-6682 or go to www.COSENTYX.com

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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