# Get appropriate patients started with the pen that is right for them



Administration flexibility with 2 easy-to-use autoinjector options<sup>1,2</sup>





Both pens are designed to help patients inject comfortably and confidently<sup>3,4†</sup>

Concealed needle

Simple, no-button activation

✓ Viewing window

Clear confirmation clicks

Check with your patient's health plan to see if additional documentation is required prior to starting them on the UnoReady pen. Keep in mind that both 150-mg devices, the Sensoready pen and prefilled syringe, are still available for patients taking either 150-mg or 300-mg doses.

\*The removable caps of the COSENTYX® 150-mg Sensoready pen and the 150-mg prefilled syringe contain natural rubber latex and should not be handled by latex-sensitive individuals. The safe use of the COSENTYX Sensoready pen or prefilled syringe in latex-sensitive individuals has not been studied.³

<sup>†</sup>The first self-injection should be performed under the supervision of a qualified healthcare professional. Patients should be trained in proper administration techniques prior to self-administration.<sup>3</sup>

PsA, psoriatic arthritis; PsO, plaque psoriasis.

#### INDICATIONS

COSENTYX® (secukinumab) is indicated for the treatment of moderate to severe plaque psoriasis (PsO) in patients 6 years and older who are candidates for systemic therapy or phototherapy.

COSENTYX is indicated for the treatment of active psoriatic arthritis (PsA) in patients 2 years of age and older.

COSENTYX is indicated for the treatment of adult patients with active ankylosing spondylitis (AS).

COSENTYX is indicated for the treatment of adult patients with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.

COSENTYX is indicated for the treatment of active enthesitisrelated arthritis (ERA) in patients 4 years of age and older. COSENTYX is indicated for the treatment of adult patients with moderate to severe hidradenitis suppurativa (HS).

# IMPORTANT SAFETY INFORMATION CONTRAINDICATIONS

COSENTYX is contraindicated in patients with a previous serious hypersensitivity reaction to secukinumab or to any of the excipients in COSENTYX. Cases of anaphylaxis and angioedema have been reported during treatment with COSENTYX.

Please see additional Important Safety
Information throughout.
Please see full <u>Prescribing Information</u>, including

Medication Guide.

# It just clicks!



# Advise patients to do the following before using their injection device<sup>3</sup>:



#### PREPARE THE PEN

Before injecting, remove carton containing the pen from the refrigerator to allow it to reach room temperature:

- Remove carton containing the UnoReady® pen
   30-45 minutes before use
- Remove carton containing the Sensoready® pen
- 15-30 minutes before use



## **CHOOSE THE INJECTION SITE**

The recommended site is the front of the thighs. Patients may also use the lower abdomen, but not the area 2 inches around the navel. If a caregiver or healthcare provider is giving the injection, they may also inject the outer upper arm (see below).



#### **CLEAN THE SITE**

Use an alcohol wipe to clean the area of the skin where they plan to inject.

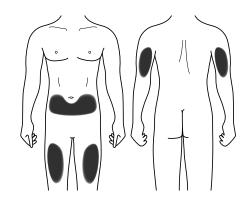
# Click, watch, click & wait<sup>3</sup>

## STEP 1 | CLICK

The injection device should be used within 5 minutes of removing the cap. Instruct the patient to hold the pen at 90 degrees to the cleaned injection site, then press and hold it **firmly against their skin**. The first click indicates the injection has started.

# STEP 2 | WATCH

A green indicator will move within the window of the injection device. It's important that the patient firmly maintains a hold of the pen against their skin while they watch the green indicator and listen for a second click.



## STEP 3 | CLICK & WAIT

The second click indicates the injection is almost complete. The patient should wait 5 seconds to make sure the green indicator has completely filled the window and stopped moving. They can then remove the injection device.



# **DISPOSAL**

Patients should put used injection devices in an FDA-cleared sharps disposal container right away after use. It is important that the patient does not dispose of them in household trash. Patients enrolled in Novartis Patient Support™ can get a free sharps container and a prepaid label to return each one when it's full.

FDA, US Food and Drug Administration.

# IMPORTANT SAFETY INFORMATION (cont) WARNINGS AND PRECAUTIONS

#### Infections

COSENTYX® may increase the risk of infections. In clinical trials, a higher rate of infections was observed in COSENTYX treated subjects compared to placebo-treated subjects. In placebo-controlled clinical trials in subjects with moderate to severe PsO, higher rates of common infections, such as nasopharyngitis (11.4% versus 8.6%), upper respiratory tract infection (2.5% versus 0.7%) and mucocutaneous infections with candida (1.2% versus 0.3%) were observed in subjects treated with COSENTYX compared to placebo-treated subjects. A similar increase in risk of infection in subjects treated with COSENTYX was seen in placebo-controlled trials in subjects with PsA, AS and nr-axSpA. The incidence of some types of infections, including fungal infections, appeared to be dose-dependent in clinical trials.

Please see additional Important Safety Information throughout.

Please see full Prescribing Information, including Medication Guide.





# **SC** Resources

For resources to help your patients start and stay on COSENTYX®, visit **cosentyx-hcpsc.com**.

# **Study Designs**

# **FUTURE 3**

FUTURE 3 was a multicenter, randomized, double-blind, double-dummy, placebo-controlled, parallel-group, 3-year study that evaluated 414 adult patients with active PsA. Patients received subcutaneous COSENTYX 150 mg (n=138), 300 mg (n=139), or placebo (n=137) at Weeks 0, 1, 2, 3, and 4, followed by the same dose every 4 weeks thereafter. At Week 16, patients who received placebo were rerandomized to COSENTYX 150 mg or 300 mg every 4 weeks based on responder status at Week 16 (nonresponders) or Week 24 (responders). Primary end point was the percentage of patients with ACR20 response at Week 24. Autoinjector usability was also examined. Safety assessments included evaluation of AEs, SAEs, and immunogenicity.<sup>2</sup>

## **MATURE**

MATURE was a 52-week, multicenter, randomized, double-blind, placebo-controlled study of the efficacy, safety, and tolerability of the 300-mg COSENTYX UnoReady® pen in 122 adult patients with moderate to severe PsO. After screening, for Treatment Period 1 (randomization through Week 12 predose), patients were randomized 2:2:1:1 to either COSENTYX 300-mg (2 mL) UnoReady pen, COSENTYX 300-mg  $2 \times 150$ -mg  $(2 \times 1 \text{ mL})$  prefilled syringes (PFS), placebo UnoReady pen (2 mL), or placebo  $(2 \times 1 \text{ mL})$  PFS. For Treatment Period 2 (Week 12 through Week 52), PASI 90 nonresponders in the placebo groups were switched to their corresponding active-drug arms. All arms started with 4 once-weekly loading doses, followed by dosing every 4 weeks. Patients switched from placebo to active drug repeated the loading doses. Primary end point was the efficacy of the COSENTYX 300-mg UnoReady pen vs placebo, with respect to both PASI 75 and IGA mod 2011 0 or 1 response (coprimary end point) at Week 12.1

ACR, American College of Rheumatology; AE, adverse event; IGA mod 2011, Investigator's Global Assessment modified 2011; PASI, Psoriasis Area and Severity Index; SAE, serious adverse event; SC, subcutaneous.

References: 1. Data on file. CAIN457A2325 (MATURE): Clinical Study Report. Novartis Pharmaceuticals Corp; August 2020. 2. Nash P, Mease PJ, McInnes IB, et al; on behalf of the FUTURE 3 study group. Efficacy and safety of secukinumab administration by autoinjector in patients with psoriatic arthritis: results from a randomized, placebo-controlled trial (FUTURE 3). *Arthritis Res Ther.* 2018;20(1):47.

3. Cosentyx. Prescribing information. Novartis Pharmaceuticals Corp. 4. Paul C, Lacour J-P, Tedremets L, et al; for the JUNCTURE Study Group. Efficacy, safety and usability of secukinumab administration by autoinjector/pen in psoriasis: a randomized, controlled trial (JUNCTURE). *J Eur Acad Dermatol Venereol.* 2015;29(6):1082-1090.

# IMPORTANT SAFETY INFORMATION (cont)

# WARNINGS AND PRECAUTIONS (cont)

# Infections (cont)

In the postmarketing setting, serious bacterial, viral, and fungal opportunistic infections, and some fatal infections have been reported in patients receiving IL-17 inhibitors including COSENTYX. Cases of Hepatitis B virus reactivation have been reported.

Exercise caution when considering the use of COSENTYX in patients with a chronic infection or a history of recurrent infection. Instruct patients to seek medical advice if signs or symptoms suggestive of an infection occur. If a patient develops a serious infection, monitor the patient closely and discontinue COSENTYX until the infection resolves.

If signs of Hepatitis B virus reactivation occur, consult a hepatitis specialist. COSENTYX is not recommended for use in patients with active viral hepatitis.

Please see additional Important Safety Information throughout.

Please see full Prescribing Information, including Medication Guide.

# **Important Safety Information (cont)**



# WARNINGS AND PRECAUTIONS (cont)

## **Pre-treatment Evaluation for Tuberculosis**

Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with COSENTYX®. Avoid administration of COSENTYX to patients with active TB infection. Initiate treatment of latent TB prior to administering COSENTYX. Consider anti-TB therapy prior to initiation of COSENTYX in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Monitor patients closely for signs and symptoms of active TB during and after treatment.

## Inflammatory Bowel Disease

Inflammatory Bowel Disease (IBD) exacerbations, in some cases serious and/or leading to discontinuation of COSENTYX, occurred in COSENTYX treated subjects during clinical trials in PsO, PsA, AS, nr-axSpA, and HS. In adult subjects with HS, the incidence of IBD was higher in subjects who received COSENTYX 300 mg every 2 weeks (Ulcerative Colitis [UC] 1 case, EAIR 0.2/100 subject-years; Crohn's Disease [CD] 1 case, EAIR 0.2/100 subject-years) compared to subjects who received COSENTYX 300 mg every 4 weeks (IBD 1 case, EAIR 0.2/100 subject-years). In addition, new onset IBD cases occurred in subjects treated with COSENTYX in clinical trials. In an exploratory trial in 59 subjects with active Crohn's disease [COSENTYX is not approved for the treatment of Crohn's disease], there were trends toward greater disease activity and increased adverse reactions in subjects treated with COSENTYX as compared to placebo-treated subjects.

Exercise caution when prescribing COSENTYX to patients with IBD. Patients treated with COSENTYX should be monitored for signs and symptoms of IBD.

# **Eczematous Eruptions**

In postmarketing reports, cases of severe eczematous eruptions, including atopic dermatitis-like eruptions, dyshidrotic eczema, and erythroderma, were reported in patients receiving COSENTYX; some cases resulted in hospitalization. The onset of eczematous eruptions was variable, ranging from days to months after the first dose of COSENTYX.

Treatment may need to be discontinued to resolve the eczematous eruption. Some patients were successfully treated for eczematous eruptions while continuing COSENTYX.

# **Hypersensitivity Reactions**

Serious hypersensitivity reactions including anaphylaxis, angioedema, and urticaria have been reported in COSENTYX treated subjects in clinical trials and in the post-marketing setting. If an anaphylactic or other serious allergic reaction occurs, immediately discontinue administration of COSENTYX and initiate appropriate therapy.

The removable caps of the COSENTYX Sensoready® pen and the COSENTYX 1 mL and 0.5 mL prefilled syringes contain natural rubber latex, which may cause an allergic reaction in latex-sensitive individuals. The safe use of the COSENTYX Sensoready pen or prefilled syringe in latex-sensitive individuals has not been studied.

#### **Immunizations**

Prior to initiating therapy with COSENTYX, consider completion of all age-appropriate immunizations according to current immunization guidelines. COSENTYX may alter a patient's immune response to live vaccines. Avoid use of live vaccines in patients treated with COSENTYX.

# MOST COMMON ADVERSE REACTIONS

Most common adverse reactions (>1%) are nasopharyngitis, diarrhea, and upper respiratory tract infection.

Please see additional Important Safety Information throughout.

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