Table 2: Clinical Outcomes at Week 12 in Adults with Plaque Psoriasis in Trials 1 and 2

	Trial 1			**Trial 2**		
	COSENTYX 300 mg (N=245) n (%)	**COSENTYX 150 mg (N=245) n (%)**	**Placebo (N=248) n (%)**	**COSENTYX 300 mg (N=327) n (%)**	**COSENTYX 150 mg (N=327) n (%)**	**Placebo (N=326) n (%)**
PASI 75 response	200 (82)	174 (71)	11 (4)	249 (76)	219 (67)	16 (5)
IGA of clear or almost clear	160 (65)	125 (51)	6 (2)	202 (62)	167 (51)	9 (3)

The results of Trials 3 and 4 are presented in Table 3.

Table 3: Clinical Outcomes at Week 12 in Adults with Plaque Psoriasis in Trials 3 and 4

	Trial 3			**Trial 4**		
	COSENTYX 300 mg (N=59) n (%)	**COSENTYX 150 mg (N=59) n (%)**	**Placebo (N=59) n (%)**	**COSENTYX 300 mg (N=60) n (%)**	**COSENTYX 150 mg (N=61) n (%)**	**Placebo (N=61) n (%)**
PASI 75 response	44 (75)	41 (69)	0 (0)	52 (87)	43 (70)	2 (3)
IGA of clear or almost clear	40 (68)	31 (53)	0 (0)	44 (73)	32 (52)	0 (0)

Examination of age, gender, and race subgroups did not identify differences in response to COSENTYX among these subgroups. Based on post-hoc sub-group analyses in patients with moderate to severe psoriasis, patients with lower body weight and lower disease severity may achieve an acceptable response with COSENTYX 150 mg.

PASI 90 response at Week 12 was achieved with COSENTYX 300 mg and 150 mg compared to placebo in 59% (145/245) and 39% (95/245) versus 1% (3/248) of subjects, respectively (Trial 1) and 54% (175/327) and 42% (137/327) versus 2% (5/326) of subjects, respectively (Trial 2). Similar results were seen in Trials 3 and 4.

With continued treatment over 52 weeks, subjects in Trial 1 who were PASI 75 responders at Week 12 maintained their responses in 81% (161/200) of the subjects treated with COSENTYX 300 mg and in 72% (126/174) of subjects treated with COSENTYX 150 mg. Trial 1 subjects who were clear or almost clear on the IGA at Week 12 also maintained their responses in 74% (119/160) of subjects treated with COSENTYX 300 mg and in 59% (74/125) of subjects treated with COSENTYX 150 mg. Similarly in Trial 2, PASI 75 responders maintained their responses in 84% (210/249) of subjects treated with COSENTYX 300 mg and in 82% (180/219) of subjects treated with COSENTYX 150 mg. Trial 2 subjects who were clear or almost clear on the IGA also maintained their responses in 80% (161/202) of subjects treated with COSENTYX 300 mg and in 68% (113/167) of subjects treated with COSENTYX 150 mg.

Among the subjects who chose to participate (39%) in assessments of patient reported outcomes, improvements in signs and symptoms related to itching, pain, and scaling, at Week 12 compared to placebo (Trials 1 and 2) were observed using the Psoriasis Symptom Diary©.

Psoriasis Lesions of Scalp

A randomized, placebo-controlled study enrolled 102 subjects with moderate to severe psoriasis lesions of scalp, defined as having a Psoriasis Scalp Severity Index (PSSI) score of greater than or equal to 12, an IGA scalp only score of 3 or greater, and at least 30% of the scalp affected. In this study, 62% of subjects had at least 50% of scalp surface area affected. The proportions of subjects achieving an IGA scalp only score of *0* or *1* (clear or almost clear) were 56.9% and 5.9% for the COSENTYX 300 mg and the placebo groups, respectively.

14.2 Psoriatic Arthritis

The safety and efficacy of COSENTYX were assessed in 1003 patients, in 2 randomized, double-blind, placebo-controlled studies (PsA1 and PsA2) in adult patients, age 18 years and older with active psoriatic arthritis (greater than 3 swollen and greater than 3 tender joints) despite non-steroidal anti-inflammatory drug (NSAID), corticosteroid or disease modifying anti-rheumatic drug (DMARD) therapy. Patients in these studies had a diagnosis of PsA of at least 5 years across both studies. At baseline, over 62% and 47% of the patients had enthesitis and dactylitis, respectively. Overall, 32% of patients discontinued previous treatment with anti-TNFα agents due to either lack of efficacy or intolerance. In addition, approximately 55% of patients from both studies had concomitant methotrexate (MTX) use. Patients with different subtypes of PsA were enrolled including polyarticular arthritis with no evidence of rheumatoid nodules (80%), asymmetric peripheral arthritis (62%), distal interphalangeal involvement (59%), spondylitis with peripheral arthritis (20%) and arthritis mutilans (7%).

PsA1 Study evaluated 397 patients, who were treated with COSENTYX 75 mg, 150 mg or 300 mg subcutaneous treatment at Weeks 0, 1, 2, 3 and 4, followed by the same dose every 4 weeks. Patients receiving placebo were re-randomized to receive COSENTYX (either 150 mg or 300 mg every 4 weeks) at Week 16 or Week 24 based on responder status. The primary endpoint was the percentage of patients achieving an ACR20 response at Week 24.

PsA2 Study evaluated 606 patients, who were treated with secukinumab 10 mg/kg, intravenous treatment (or placebo) at Weeks 0, 2, and 4, followed by either 75 mg or 150 mg subcutaneous COSENTYX treatment (or placebo) every 4 weeks. Patients receiving placebo were re-randomized to receive COSENTYX (either 75 mg or 150 mg every 4 weeks) at Week 16 or Week 24 based on responder status.

Clinical Response

In PsA1, patients treated with 150 mg or 300 mg COSENTYX demonstrated a greater clinical response including ACR20, ACR50, and ACR70 compared to placebo at Week 24 (Table 4). Responses were similar in patients regardless of concomitant methotrexate treatment. Responses were seen regardless of prior anti-TNFα exposure.

In patients with coexistent plaque psoriasis receiving COSENTYX (n=99), the skin lesions of psoriasis improved with treatment, relative to placebo, as measured by the Psoriasis Area Severity Index (PASI).

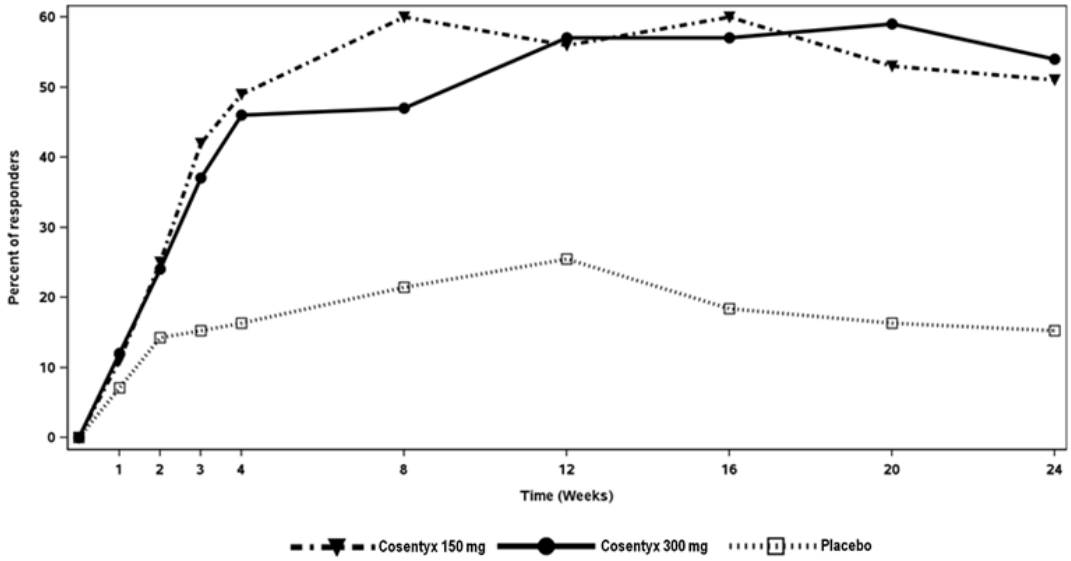
Table 4: Responses[a] in PsA1 Study at Week 16 and Week 24

	COSENTYX 150 mg (N=100)	COSENTYX 300 mg (N=100)	Placebo (N=98)	Difference from placebo (95% CI)	
				COSENTYX 150 mg	COSENTYX 300 mg
ACR20 response					
Week 16 (%)	60	57	18	42 (30, 54)	38 (26, 51)
Week 24 (%)	51	54	15	36 (24, 48)	39 (27, 51)
ACR50 response					
Week 16 (%)	37	35	6	31 (21, 42)	28 (18, 39)
Week 24 (%)	35	35	7	28 (18, 38)	28 (17, 38)
ACR70 response					
Week 16 (%)	17	15	2	15 (7, 23)	13 (5, 20)
Week 24 (%)	21	20	1	20 (12, 28)	19 (11, 27)

[a] Patients who met escape criteria (less than 20% improvement in tender or swollen joint counts) at Week 16 were considered non-responders

The percentage of patients achieving ACR20 response by visit is shown in Figure 1. Patients on placebo who received COSENTYX without a loading regimen achieved similar ACR20 responses over time (data not shown).

Figure 1: Percent of Patients Achieving ACR 20 Response[a] in PsA1 Study Through Week 24



[a]Patients who met escape criteria (less than 20% improvement in tender or swollen joint counts) at Week 16 were considered non-responders

The improvements in the components of the ACR response criteria are shown in Table 5.

Table 5: Mean Change from Baseline in ACR Components at Week 16[a] (PsA1 Study)

	COSENTYX 150 mg (N=100)	**COSENTYX 300 mg** (N=100)	**Placebo** (N=98)
No. of Swollen Joints			
Baseline	12.0	11.2	12.1
Mean change at Week 16	-4.86	-5.83	-3.22
Number of Tender Joints			
Baseline	24.1	20.2	23.5
Mean change at Week 16	-10.70	-10.01	-1.77
Patient's assessment of Pain			
Baseline	58.9	57.7	55.4
Mean change at Week 16	-22.91	-23.97	-7.98
Patient Global Assessment			
Baseline	62.0	60.7	57.6
Mean change at Week 16	-25.47	-25.40	-8.25
Physician Global Assessment			
Baseline	56.7	55.0	55.0
Mean change at Week 16	-29.24	-34.71	-14.95
Disability Index (HAQ)			
Baseline	1.2200	1.2828	1.1684
Mean change at Week 16	-0.45	-0.55	-0.23
CRP (mg/L)			
Baseline	14.15	10.88	7.87
Mean Change at Week 16[b]	-8.41	-7.21	0.79

[a]Week 16 rather than Week 24 data are displayed to provide comparison between arms prior to placebo escape to COSENTYX.
[b]Mean Change based upon observed data

Improvements in enthesitis and dactylitis scores were observed in each COSENTYX group compared to placebo at Week 24.

Physical Function and Health Related Quality of Life

Improvement in physical function as assessed by Health Assessment Questionnaire-Disability Index (HAQ-DI) demonstrated that the proportion of patients who achieved at least -0.3 improvement in HAQ-DI score from baseline was greater in the COSENTYX 150 mg and 300 mg groups compared to placebo at Week 16 and 24. At Week 16 in PsA1 study, estimated mean change from baseline was -0.23 in the placebo group compared with -0.45 in the COSENTYX 150 mg group and -0.55 in the COSENTYX 300 mg group.

14.3 Ankylosing Spondylitis

The safety and efficacy of COSENTYX were assessed in 590 patients in two randomized, double-blind, placebo-controlled studies (AS1 and AS2) in adult patients 18 years of age and older with active ankylosing spondylitis. Patients had active disease as defined by the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) greater or equal to 4 despite non-steroidal anti-inflammatory drug (NSAID), corticosteroid or disease modifying anti-rheumatic drug (DMARD) therapy. At baseline, approximately 14% and 26% used concomitant methotrexate or sulfasalazine, respectively. Overall, 33% of patients discontinued previous treatment with anti-TNFα agents due to either lack of efficacy or intolerance.

AS1 Study evaluated 219 patients, who were treated with COSENTYX 75 mg or 150 mg subcutaneous treatment at Weeks 0, 1, 2, 3 and 4, followed by the same dose every 4 weeks. At Week 16, patients receiving placebo were re-randomized to either COSENTYX 75 mg or 150 mg every 4 weeks. The primary endpoint was the percentage of patients achieving an ASAS20 response at Week 16.

AS2 Study evaluated 371 patients, who were treated with secukinumab 10 mg/kg intravenous treatment at Weeks 0, 2, and 4 (for both treatment arms) or placebo, followed by either 75 mg or 150 mg subcutaneous COSENTYX treatment

every 4 weeks or placebo. Patients receiving placebo were re-randomized to receive COSENTYX (either 75 mg or 150 mg every 4 weeks) at Week 16 or Week 24 based on responder status.

Clinical Response

In AS1, patients treated with 150 mg COSENTYX demonstrated greater improvements in ASAS20 and ASAS40 responses compared to placebo at Week 16 (Table 6). Responses were similar in patients regardless of concomitant therapies.

Table 6: ASAS20 and ASAS40 Responses in All AS Patients at Week 16 in Study AS1

	COSENTYX 150 mg (n = 72)	**Placebo (n = 74)**	**Difference from placebo (95% CI)**
ASAS20 response, %	61	28	33 (18, 48)
ASAS40 response, %	36	11	25 (12, 38)

The improvements in the main components of the ASAS20 response criteria and other measures of disease activity are shown in Table 7.

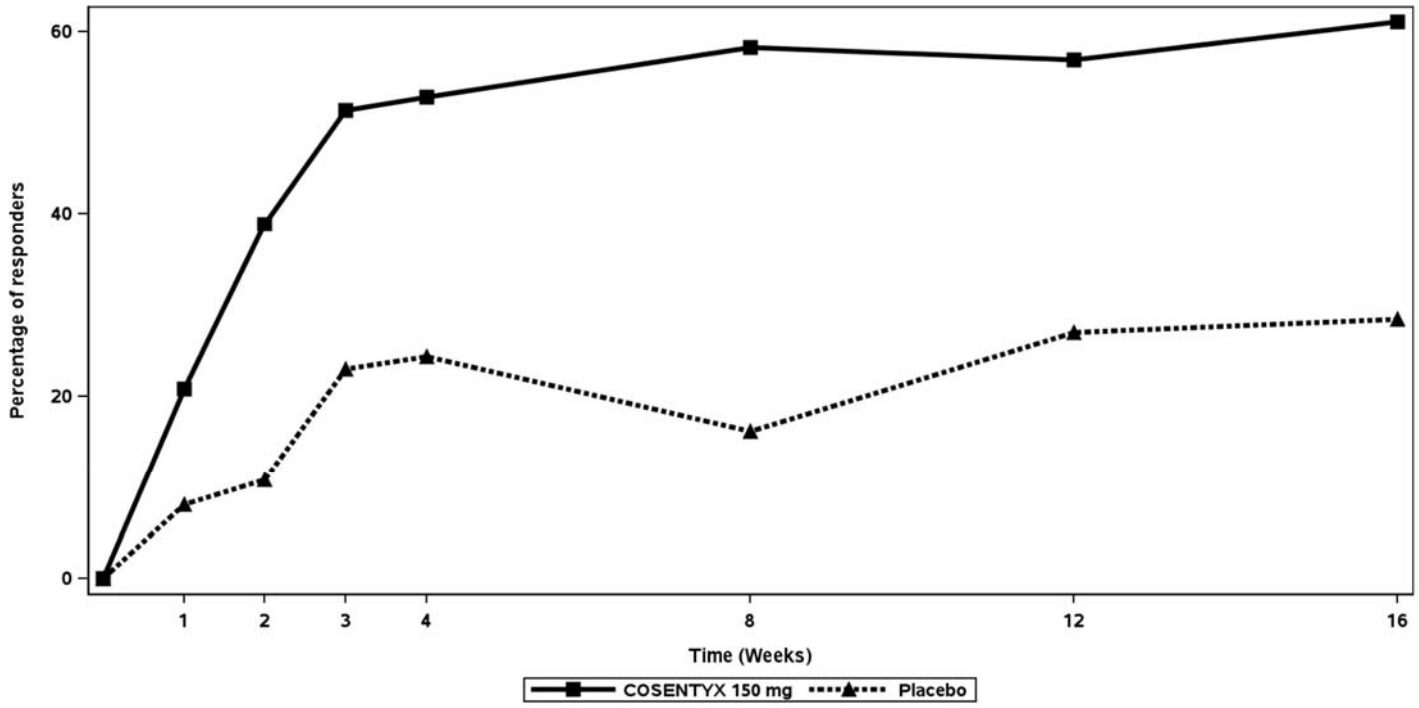
Table 7: ASAS20 Components and Other Measures of Disease Activity at Week 16 (AS1 Study)

	COSENTYX 150 mg (N = 72)		**Placebo (N = 74)**	
	Baseline	Week 16 change from baseline	Baseline	Week 16 change from baseline
ASAS20 Response criteria				
-Patient Global Assessment of Disease Activity (0-100 mm)[1]	67.5	-27.7	70.5	-12.9
-Total spinal pain (0-100 mm)	66.2	-28.5	69.2	-10.9
-BASFI (0-10)[2]	6.2	-2.2	6.1	-0.7
-Inflammation (0-10)[3]	6.5	-2.5	6.5	-0.8
BASDAI Score[4]	6.6	-2.2	6.8	-0.9
BASMI[5]	3.6	-0.51	3.9	-0.22
hsCRP[6] (mg/L) Mean Change at Week 16	27.0	-17.2	15.9	0.8

1. Percent of subjects with at least a 20% and 10 unit improvement measured on a Visual Analog Scale (VAS) with 0= none, 100= severe
2. Bath Ankylosing Spondylitis Functional Index
3. Inflammation is the mean of two patient-reported stiffness self-assessment in BASDAI
4. Bath Ankylosing Spondylitis Disease Activity Index
5. Bath Ankylosing Spondylitis Metrology Index
6. High sensitivity C-reactive protein / mean change based upon observed data

The percent of patients achieving ASAS20 responses by visit is shown in Figure 2. Patients on placebo who received COSENTYX without a loading regimen achieved similar ASAS20 responses over time (data not shown).

Figure 2: ASAS20 Responses in all AS1 Study Patients Over Time Up to Week 16



COSENTYX treated patients showed improvement compared to placebo-treated patients in health-related quality of life as assessed by ASQoL at Week 16.

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

COSENTYX Sensoready pen:

• NDC 0078-0639-41: Carton of two 150 mg/mL (300 mg dose) Sensoready pens (injection)

• NDC 0078-0639-68: Carton of one 150 mg/mL single-use Sensoready pen (injection)

COSENTYX prefilled syringe:

• NDC 0078-0639-98: Carton of two 150 mg/mL (300 mg dose) single-use prefilled syringes (injection)

• NDC 0078-0639-97: Carton of one 150 mg/mL single-use prefilled syringe (injection)

The removable cap of the COSENTYX Sensoready pen and prefilled syringe contains natural rubber latex. Each Sensoready pen and prefilled syringe is equipped with a needle safety guard.

COSENTYX vial (for healthcare professional use only):

• NDC 0078-0657-61: Carton of one 150 mg lyophilized powder in a single-use vial (for injection)

16.2 Storage and Handling

COSENTYX Sensoready pens, prefilled syringes and vials must be refrigerated at 2ºC to 8ºC (36ºF to 46ºF). Keep the product in the original carton to protect from light until the time of use. Do not freeze. To avoid foaming do not shake. COSENTYX does not contain a preservative; discard any unused portion.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read FDA-approved patient labeling (Medication Guide and Instructions for Use).

Patient Counseling

Instruct patients to read the Medication Guide before starting COSENTYX therapy and to re-read the Medication Guide each time the prescription is renewed.

Advise patients of the potential benefits and risks of COSENTYX.

Infections

Inform patients that COSENTYX may lower the ability of their immune system to fight infections. Instruct patients of the importance of communicating any history of infections to the doctor and contacting their doctor if they develop any symptoms of infection *[see Warnings and Precautions (5.1)]*.

Hypersensitivity

Advise patients to seek immediate medical attention if they experience any symptoms of serious hypersensitivity reactions *[see Warnings and Precautions (5.4)]*.

Instruction on Injection Technique

Perform the first self-injection under the supervision of a qualified healthcare professional. If a patient or caregiver is to administer COSENTYX, instruct him/her in injection techniques and assess their ability to inject subcutaneously to ensure the proper administration of COSENTYX *[see Medication Guide and Instructions for Use]*.

Instruct patients or caregivers in the technique of proper syringe and needle disposal, and advise them not to reuse these items. Instruct patients to inject the full amount of COSENTYX (1 or 2 subcutaneous injections of 150 mg) according to the directions provided in the Medication Guide and Instructions for Use. Dispose of needles, syringes and pens in a puncture-resistant container.

Manufactured by:
Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936

US License No. 1244

T2018-01

MEDICATION GUIDE

COSENTYX® (koe-sen-tix)
(secukinumab) Injection

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.

- 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 take 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 adults:

- with moderate to severe plaque psoriasis 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)
- with active psoriatic arthritis
- with active ankylosing spondylitis

COSENTYX may improve your psoriasis, psoriatic arthritis and ankylosing spondylitis but it may also lower the ability of your immune system to fight infections.

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

Do not take COSENTYX:

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 taking 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 prefilled syringe contains latex.
- have recently received or are scheduled to receive an immunization (vaccine). People who take COSENTYX **should not** receive live vaccines.
- have any other medical conditions
- 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 should I use COSENTYX?

See 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 Sensoready pens and prefilled syringes.

- Use COSENTYX exactly as prescribed by your healthcare provider.
- 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.
- COSENTYX comes in a Sensoready pen or prefilled syringe that you or your caregiver may use at home to give injections. Your healthcare provider will decide which type of COSENTYX is best for you to use at home.
- Your healthcare provider will prescribe the dose of COSENTYX that is right for you.
  - If your prescribed dose of COSENTYX is **150 mg**, you must give **1 injection** of COSENTYX for each dose.
  - If your prescribed dose of COSENTYX is **300 mg**, you must give **2 injections** for each dose.
- 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 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 go to the nearest emergency room right away.

What are the possible side effects of COSENTYX?

See **"What is the most important information I should know about 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.
- **Serious allergic reactions.** Get emergency medical help right away if you get any of the following symptoms of a serious allergic reaction:
  - feel faint
  - swelling of your face, eyelids, lips, mouth, tongue, or throat
  - trouble breathing or throat tightness
  - chest tightness
  - skin rash

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

The most common side effects of COSENTYX include:

- cold symptoms
- diarrhea
- upper respiratory 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.
- Do not freeze COSENTYX.
- Do not shake 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 healthcare provider or pharmacist for information about COSENTYX that is written for health professionals.

What are the ingredients in COSENTYX?

Active ingredient: secukinumab

Inactive ingredients: Sensoready pen and prefilled syringe: L-histidine/histidine hydrochloride monohydrate, L-methionine, polysorbate 80, trehalose dihydrate, and sterile water for injection.

Vial: L-histidine/histidine hydrochloride monohydrate, polysorbate 80, and sucrose.

Manufactured by: Novartis Pharmaceuticals Corporation East Hanover, New Jersey 07936
T2016-02
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 Revised: January 2018

INSTRUCTIONS FOR USE
COSENTYX® (koe-sen-tix)

(secukinumab)

For Injection

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

IMPORTANT:

- 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.
- Throw away (dispose of) the used syringe right away after use. Do not re-use a syringe. See **"How should I dispose of a used syringe?"** at the end of this Instructions for Use.

How should I store COSENTYX?

- Store the vial of COSENTYX in the refrigerator between 2°C to 8°C (36°F to 46°F).

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

Instructions for reconstitution of COSENTYX 150 mg for injection:

Step 1. Remove the vial of COSENTYX 150 mg for injection from the refrigerator and allow to stand for 15 to 30 minutes to reach room temperature. Ensure the Sterile Water for Injection (SWFI) is at room temperature.

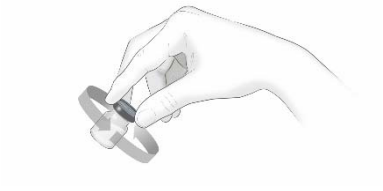
Step 2. Reconstitute the lyophilized powder by slowly injecting 1 mL of Sterile Water for Injection (SWFI) into the vial. Direct the stream of SWFI onto the lyophilized powder (**See Figure A**).

Figure A

Step 3. Tilt the vial to an angle of approximately 45 degrees and gently rotate between the fingertips for approximately 1 minute. Do not shake or invert the vial (**See Figure B**).

Step 4. 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.

Figure B



Step 5. Tilt the vial to an angle of approximately 45 degrees and gently rotate between the fingertips for approximately 1 minute. Do not shake or invert the vial (**See Figure B**).

Step 6. 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 visible particles, is cloudy or is discolored.

Step 7. Prepare the required number of vials (1 vial for the 150 mg dose or 2 vials for the 300 mg dose).

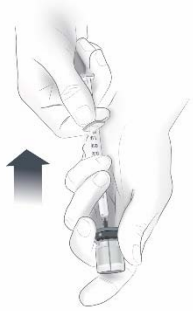
After preparation, use the solution for subcutaneous injection immediately or store at 2°C to 8 °C (36°F to 46°F) for up to 24 hours. Do not freeze. After storage at 2°C to 8°C (36°F to 46°F), allow the reconstituted

solution to come to room temperature (15 to 30 minutes) before administration. Administer the solution within 1 hour after removal from the 2°C to 8°C (36°F to 46°F) storage.

Instructions for administration of COSENTYX solution:

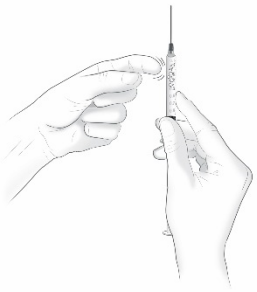
Step 1. Tilt the vial to an angle of approximately 45 degrees and position the needle tip at the very bottom of the solution in the vial when drawing the solution into the syringe. DO NOT invert the vial.
Step 2. Carefully withdraw slightly more than 1 mL of the solution for subcutaneous injection from the vial into a 1 mL graduated disposable syringe using a suitable needle (e.g., 21G x 2") **(See Figure C).** This needle will only be used for withdrawing COSENTYX into the disposable syringe. Prepare the required number of syringes (1 syringe for the 150 mg dose or 2 syringes for the 300 mg dose).

Figure C



Step 3. With the needle pointing upward, gently tap the syringe to move any air bubbles to the top **(See Figure D).**

Figure D

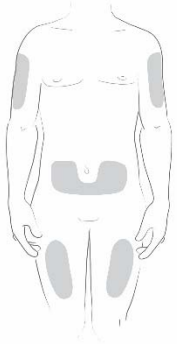


Step 4. Replace the attached needle with a 27G x ½" needle **(See Figure E).**
Step 5. Expel the air bubbles and advance the plunger to the 1 mL mark.
Step 6. Clean the injection site with an alcohol wipe.

Figure E

Step 7. 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 **(See Figure F).** 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, or in an area of skin that is affected by psoriasis. Avoid areas with scars or stretch marks.

Figure F



INSTRUCTIONS FOR USE
COSENTYX® (koe-sen-tix)
(secukinumab)
Injection
Sensoready® Pen

Be sure that you read, understand, and follow this Instructions for Use before injecting COSENTYX. Your healthcare provider should show you how to prepare and inject COSENTYX properly using the Sensoready Pen before you use it for the first time. Talk to your healthcare provider if you have any questions.

Important:

- **Do not use** the COSENTYX Sensoready Pen if either the seal on the outer carton or the seal on the pen is broken. Keep the COSENTYX Sensoready Pen in the sealed outer carton until you are ready to use it.
- Inject COSENTYX **within 1 hour** after taking it out of the refrigerator.
- **Do not shake** the COSENTYX Sensoready Pen.
- The caps of the Sensoready Pens contain latex. **Do not handle the Sensoready Pens if you are sensitive to latex.**
- If you drop your COSENTYX Sensoready Pen, **do not use** it if the Sensoready Pen looks damaged, or if you dropped it with the cap removed.
- Throw away (dispose of) the used COSENTYX Sensoready Pen right away after use. **Do not re-use a COSENTYX Sensoready Pen.** See "How should I dispose of used COSENTYX Sensoready Pens?" at the end of this Instructions for Use.

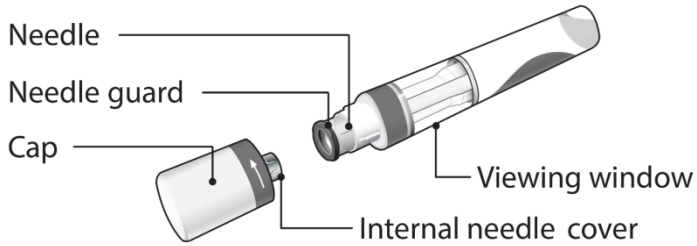
How should I store COSENTYX?

- Store your carton of COSENTYX Sensoready Pen in a refrigerator, between 36°F to 46°F (2°C to 8°C).
- Keep COSENTYX Sensoready Pen in the original carton until ready to use to protect from light.
- Do not freeze COSENTYX Sensoready Pen.

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

COSENTYX Sensoready Pen parts (see Figure A):

Figure A



The COSENTYX Sensoready Pen is shown above with the cap removed. **Do not** remove the cap until you are ready to inject.

What you need for your injection:

Included in the carton:
A new COSENTYX Sensoready Pen (**see Figure B**).
Each COSENTYX Sensoready Pen contains 150 mg of COSENTYX.

- If your **prescribed dose** of COSENTYX is **150 mg**, you must give **1 injection.**
- If your **prescribed dose** of COSENTYX is **300 mg**, you must give **2 injections**.

Figure B

Not included in the carton **(see Figure C)**:

- 1 Alcohol wipe
- 1 Cotton ball or gauze
- Sharps disposal container.

Figure C

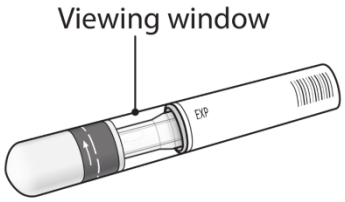
See "**How should I dispose of used COSENTYX Sensoready Pen**?" at the end of this Instructions for Use.

Before your injection:

Take the COSENTYX Sensoready Pen out of the refrigerator **15 to 30 minutes before injecting** to allow it to reach room temperature.

Step 1. Important safety checks before you inject (see Figure D):

Figure D



- Look through the viewing window. The liquid should be clear. Its color may vary from colorless to slightly yellow.

  Do not use if the liquid contains visible particles, is cloudy or is discolored. You may see a small air bubble, which is normal.
- Look at the **expiration date (EXP)** on your Sensoready Pen. **Do not use** your COSENTYX Sensoready Pen if the expiration date has passed.

Contact your pharmacist if the COSENTYX Sensoready Pen fails any of these checks.

Step 2. 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 your navel (belly button) **(see Figure E).**
- 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, or in an area of skin that is affected by psoriasis. Avoid areas with scars or stretch marks.

- If a **caregiver** or **healthcare provider** is giving you your injection, they may also inject into your outer upper arm **(see Figure F).**

Figure E

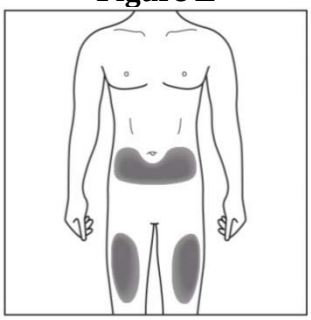
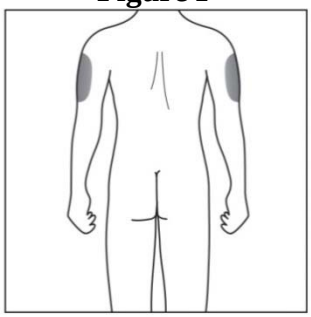


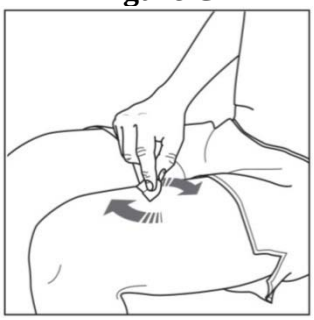
Figure F



Step 3. Cleaning your injection site:

- Wash your hands well with soap and water.
- Using a circular motion, clean the injection site with the alcohol wipe. Leave it to dry before injecting **(see Figure G).**
- Do not touch the cleaned area again before injecting.

Figure G

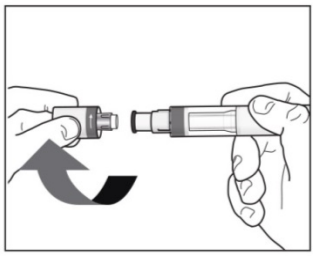


Your injection:

Step 4. Removing the cap:

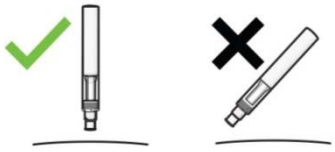
- Only remove the cap when you are ready to use the COSENTYX Sensoready Pen.
- Twist off the cap in the direction of the arrow **(see Figure H)**.
- Throw away the cap. **Do not try to re-attach the cap.**
- Use the COSENTYX Sensoready Pen within 5 minutes of removing the cap.

Figure H



Step 5. Holding your COSENTYX Sensoready Pen:

- Hold the COSENTYX Sensoready Pen at 90 degrees to the cleaned injection site **(see Figure I).**



Correct **Incorrect**

Figure I

Important: During the injection you will hear **2 loud clicks**:

- The **1st click** indicates that **the injection has started**.

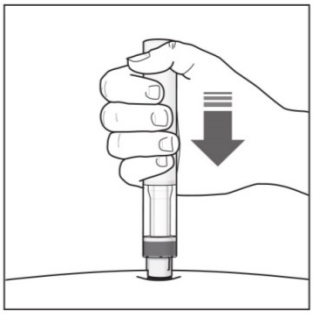
- Several seconds later a **2nd click** will indicate that **the injection is almost finished**.

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

Step 6. Starting your injection:

- Press the COSENTYX Sensoready Pen firmly against the skin to start the injection **(see Figure J).**
- 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.

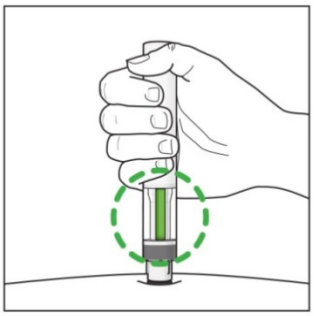
Figure J



Step 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 **(see Figure K).**
- The COSENTYX Sensoready Pen can now be removed.

Figure K



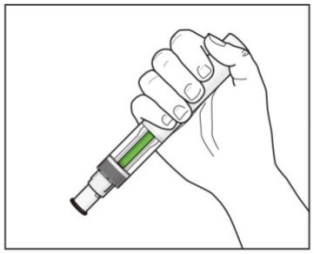
After your injection:

Step 8. Check the green indicator fills the window (see Figure L):

- This means the medicine has been delivered. Contact your healthcare provider 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.

If your prescribed dose of COSENTYX is 300 mg, repeat steps 1 through 8 with a new COSENTYX Sensoready Pen.

Figure L



How should I dispose of used COSENTYX Sensoready Pens?

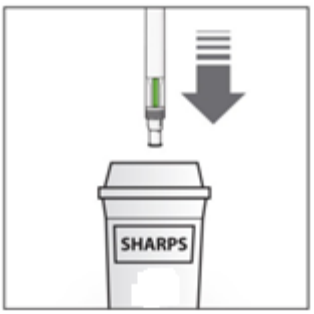
Step 9. Put your used Sensoready Pens in a FDA-cleared sharps disposal container right away after use **(see Figure M). Do not throw away (dispose of)** Sensoready Pens in your household trash.

If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:

- made of a heavy-duty plastic,
- can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
- upright and stable during use,
- leak-resistant, and
- properly labeled to warn of hazardous waste inside the container.

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles, syringes, and Sensoready Pens. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: http://www.fda.gov/safesharpsdisposal.

Figure M



This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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