

## IMPORTANT SAFETY INFORMATION

SELARSDI™ (ustekinumab-aekn) Injection is a prescription medicine that affects your immune system. SELARSDI can increase your chance of having serious side effects including:

#### **Serious Infections**

SELARSDI may lower your ability to fight infections and may increase your risk of infections. While taking ustekinumab products, some people have serious infections, which may require hospitalization, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses.

- Your doctor should check you for TB before starting SELARSDI and watch you closely for signs and symptoms of TB during treatment with SELARSDI.
- If your doctor feels that you are at risk for TB, you may be treated for TB before and during treatment with SELARSDI.

You should not start taking SELARSDI if you have any kind of infection unless your doctor says it is okay.

Please see Important Safety Information throughout and the full Prescribing Information and Medication Guide for SELARSDI.





# WHAT IS SELARSDI™?

SELARSDI is an FDA-approved biosimilar that can be taken in place of Stelara®, whether you're new to therapy or currently taking Stelara.

## What is a biosimilar?



A biosimilar is an FDA-approved version of an original biologic designed to offer the same treatment benefits

 The FDA makes sure biosimilars are as safe and effective as the original biologic by approving biosimilars after a careful review of data, studies, and tests

SELARSDI has been carefully tested and is approved by the FDA as a biosimilar to Stelara

## How are SELARSDI and Stelara alike?



SELARSDI and Stelara are made in the same way



SELARSDI and Stelara have similar treatment benefits and risks



SELARSDI and Stelara are given at the same strength and dosage

## IMPORTANT SAFETY INFORMATION (cont'd)

## Before starting SELARSDI, tell your doctor if you:

- 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 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
- · feel very tired



## WHAT DOES SELARSDI™ DO?

## SELARSDI is used to treat the same conditions as Stelara®

#### **CROHN'S DISEASE**

Adults 18 years and older with moderately to severely active Crohn's disease

## **PLAQUE PSORIASIS**

Adults and children 6 years and older with moderate to severe plaque psoriasis who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet light alone or with pills)

#### **ULCERATIVE COLITIS**

Adults 18 years and older with moderately to severely active ulcerative colitis

#### **PSORIATIC ARTHRITIS**

Adults and children 6 years and older with active psoriatic arthritis

SELARSDI can be taken in place of Stelara for any of the above indications

## **IMPORTANT SAFETY INFORMATION (cont'd)**

Before starting SELARSDI, tell your doctor if you: (cont'd)

- are being treated for an infection or have any open cuts.
- get a lot of infections or have infections that keep coming back.
- have TB, or have been in close contact with someone with TB.

After starting SELARSDI, call your doctor right away if you have any symptoms of an infection (see above). These may be signs of infections such as chest infections, or skin infections or shingles that could have serious complications. SELARSDI can make you more likely to get infections or make an infection that you have worse. People who have a genetic problem where the body does not make any of the proteins interleukin 12 (IL-12) and interleukin 23 (IL-23) are at a higher risk for certain serious infections that can spread throughout the body and cause death. People who take SELARSDI may also be more likely to get these infections.

Please see Important Safety Information throughout and the full <u>Prescribing Information</u> and Medication Guide for SELARSDI.



# WE'RE HERE FOR YOU

# Teva Shared Solutions® for Biosimilars provides a seamless support experience



Teva Shared Solutions offers a range of services

- Understanding insurance benefits
- ◆ Financial assistance
- Injection education

Enroll at SELARSDI.com or call 1-888-587-3263

# TEVA IS COMMITTED TO HELPING SUPPORT YOU ON YOUR TREATMENT JOURNEY

## IMPORTANT SAFETY INFORMATION (cont'd)

#### **Cancers**

SELARSDI may decrease the activity of your immune system and increase your risk for certain types of cancers. Tell your doctor if you have ever had any type of cancer. Some people who had risk factors for skin cancer developed certain types of skin cancers while receiving ustekinumab products. During your treatment with SELARSDI, tell your doctor if you have any new skin growths.

## Posterior Reversible Encephalopathy Syndrome (PRES)

PRES is a rare condition that affects the brain and can cause death. The cause of PRES is not known. If PRES is found early and treated, most people recover. Tell your doctor right away if you have any new or worsening medical problems including: headache, seizures, confusion, and vision problems.



# YOU CAN SAVE WITH SELARSDI™

## Eligible patients may pay as little as \$0 for SELARSDI

Enroll in the SELARSDI Savings Program to receive cost support and pay as little as \$0 for your medicine.



#### Eligibility requirements

- Offer is available for patients with commercial insurance only
- Offer is NOT available for patients eligible for Medicare, Medicaid, or any other form of government insurance coverage

For more information on the SELARSDI Savings Program, go to SELARSDI.com/savings-and-support, or call 1-844-211-7047 to enroll

## IMPORTANT SAFETY INFORMATION (cont'd)

## **Serious Allergic Reactions**

Serious allergic reactions can occur. Stop using SELARSDI and get medical help right away if you have any symptoms of a serious allergic reaction such as: feeling faint, swelling of your face, eyelids, tongue, throat, chest tightness, or skin rash.

## **Lung Inflammation**

Cases of lung inflammation have happened in some people who receive ustekinumab products and may be serious. These lung problems may need to be treated in a hospital. Tell your doctor right away if you develop shortness of breath or a cough that doesn't go away during treatment with SELARSDI.

## What is SELARSDI™ (ustekinumab-aekn) Injection?

SELARSDI is a prescription medicine used to treat:

- adults and children 6 years and older with moderate to severe psoriasis who may benefit from taking
  injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet light alone or with pills).
- adults and children 6 years and older with active psoriatic arthritis.
- adults 18 years and older with moderately to severely active Crohn's disease.
- adults 18 years and older with moderately to severely active ulcerative colitis.

It is not known if SELARSDI is safe and effective in children less than 6 years of age.

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- feel very tired
- are being treated for an infection or have any open cuts.
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Injection • 45mg/0.5mL • 90mg/mL

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## Before receiving SELARSDI, tell your doctor about all of your medical conditions, including if you:

- have any of the conditions or symptoms listed above for serious infections, cancers, PRES, serious allergic reactions or lung inflammation.
- ever had an allergic reaction to ustekinumab products or any of ingredients in SELARSDI. Ask your doctor if you are not sure.
- have recently received or are scheduled to receive an immunization (vaccine). People who take SELARSDI should not receive live vaccines. Tell your doctor if anyone in your house needs a live vaccine. The viruses used in some types of live vaccines can spread to people with a weakened immune system, and can cause serious problems. You should not receive the BCG vaccine during the one year before receiving SELARSDI or one year after you stop receiving SELARSDI.
- have any new or changing lesions within psoriasis areas or on normal skin.
- are receiving or have received allergy shots, especially for serious allergic reactions. Allergy shots may not work as well for you during treatment with SELARSDI. SELARSDI may also increase your risk of having an allergic reaction to an allergy shot.
- receive or have received phototherapy for your psoriasis.
- are pregnant or plan to become pregnant. It is not known if SELARSDI can harm your unborn baby. You and your doctor should decide if you will receive SELARSDI.
- received SELARSDI while you were pregnant. It is important that you tell your baby's healthcare provider before any vaccinations are given to your baby.
- are breastfeeding or plan to breastfeed. SELARSDI can pass into your breast milk. Talk to your doctor about the best way to feed your baby if you receive SELARSDI.

**Tell your doctor 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 them to show your doctor and pharmacist when you get a new medicine.

## When prescribed SELARSDI:

- Use SELARSDI exactly as your doctor tells you to.
- SELARSDI is intended for use under the guidance and supervision of your doctor. In children 6 years and older, it is recommended that SELARSDI be administered by a healthcare provider. If your doctor decides that you or a caregiver may give your injections of SELARSDI at home, you should receive training on the right way to prepare and inject SELARSDI. Your doctor will determine the right dose of SELARSDI for you, the amount for each injection, and how often you should receive it. Do not try to inject SELARSDI yourself until you or your caregiver have been shown how to inject SELARSDI by your doctor or nurse.

Common side effects of SELARSDI include: nasal congestion, sore throat, and runny nose, upper respiratory infections, fever, headache, tiredness, itching, nausea and vomiting, redness at the injection site, vaginal yeast infections, urinary tract infections, sinus infection, bronchitis, diarrhea, and stomach pain.

These are not all of the possible side effects with SELARSDI. Call your doctor for medical advice about side Effects. Ask your doctor or pharmacist for more information.

To report SUSPECTED ADVERSE REACTIONS, contact Teva Pharmaceuticals at 1-888-483-8279 or FDA at 1-800-FDA-1088 or <a href="https://www.fda.gov/medwatch">www.fda.gov/medwatch</a>.



# STRIKINGLY SIMILAR



For instructions on using the SELARSDI™ prefilled syringe, see Instructions for Use



Click to watch a video

on how to use the SELARSDI prefilled syringe



## IMPORTANT SAFETY INFORMATION (cont'd)

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