MEDICATION GUIDE

LEQSELVI™ [lek-sel-vee]

(deuruxolitinib)

tablets, for oral use

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

LEQSELVI may cause serious side effects, including:

1. **Serious Infections.** LEQSELVI is a medicine that affects your immune system. LEQSELVI can lower the ability of your immune system to fight infections. Some people have had serious infections during treatment with LEQSELVI, caused by bacteria, fungi or viruses that can spread throughout the body. Some people may die from these infections.
   - Your healthcare provider should test you for TB before starting treatment with LEQSELVI.
   - Your healthcare provider should watch you closely for signs and symptoms of TB during treatment with LEQSELVI.

   You should not start taking LEQSELVI if you have any kind of infection unless your healthcare provider tells you it is okay. You may be at a higher risk of developing shingles (herpes zoster).

   Before starting LEQSELVI, 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 diabetes, chronic lung disease, HIV, or a weak immune system. People with these conditions have a higher chance for infections.
   - have TB or have been in close contact with someone with TB.
   - have had shingles (herpes zoster).
   - have had hepatitis B or hepatitis C.
   - live, or have lived, or have traveled to certain parts of the country (such as Ohio and Mississippi River valleys and the Southwest) where there is an increased chance for getting certain kinds of fungal infections. These infections may happen or become more severe if you use LEQSELVI. Ask your healthcare provider if you do not know if you have lived in an area where these infections are common.
   - think you have an infection or have symptoms of an infection such as:
     - fever, sweating, or chills
     - shortness of breath
     - warm, red or painful skin or sores on your body
     - burning when you urinate or urinating more often than normal
     - muscle aches
     - blood in your phlegm
     - diarrhea or stomach pain
     - cough
     - weight loss
     - feeling very tired

   After starting LEQSELVI, call your healthcare provider right away if you have any symptoms of an infection. LEQSELVI can make you more likely to get infections or make any infections that you have worse. If you get a serious infection, your healthcare provider may stop your treatment with LEQSELVI until your infection is controlled.
2. **Increased risk of death in people 50 years of age and older who have at least 1 heart disease (cardiovascular) risk factor and are taking a medicine in the class of medicines called Janus kinase (JAK) inhibitors. LEQSELVI is a JAK inhibitor medicine.**
3. **Cancer and immune system problems.** LEQSELVI may increase your risk of certain cancers by changing the way your immune system works.
   - Lymphoma and other cancers, including skin cancers, can happen in people taking LEQSELVI. People taking a medicine in the class of medicines called Janus kinase (JAK) inhibitors have a higher risk of certain cancers including lymphoma and lung cancer, especially if you are a current or past smoker.
   - Follow your healthcare provider's advice about having your skin checked for skin cancer during treatment with LEQSELVI.

   Tell your healthcare provider if you have ever had any type of cancer.
4. **Increased risk of major cardiovascular events such as heart attack, stroke or death in people 50 years of age and older who have at least 1 heart disease (cardiovascular) risk factor and taking a medicine in the class of medicines called JAK inhibitors, especially if you are a current or past smoker.**

   Get emergency help right away if you get any symptoms of a heart attack or stroke during treatment with LEQSELVI, including**:**
   - discomfort in the center of your chest that lasts for more than a few minutes, or that goes away and comes back
   - severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw
   - pain or discomfort in your arms, back, neck, jaw, or stomach
   - shortness of breath with or without chest discomfort
   - breaking out in a cold sweat

- nausea or vomiting
- feeling lightheaded
- weakness in one part or on one side of your body
- slurred speech

5. **Blood clots.** Blood clots in the veins of your legs (deep vein thrombosis, DVT), lungs (pulmonary embolism, PE) or brain (cerebral venous sinus thrombosis, CVT) can happen in some people during treatment with LEQSELVI. This may be life-threatening and may cause death. Blood clots in the veins of the legs (DVT) and lungs (PE) have happened more often in people who are 50 years of age and older and with at least 1 heart disease (cardiovascular) risk factor taking a medicine in the class of medicines called Janus kinase (JAK) inhibitors.
   - Tell your healthcare provider if you have had blood clots in the veins of your legs, lungs, or brain in the past.
   - Stop taking LEQSELVI and tell your healthcare provider or get medical help right away if you get any signs or symptoms of blood clots during treatment with LEQSELVI, including:
     - swelling, pain or tenderness in one or both legs
     - sudden, unexplained chest or upper back pain
     - shortness of breath or difficulty breathing
     - severe headaches
6. **Tears (perforation) in the stomach or intestines.**
   - Tell your healthcare provider if you have had diverticulitis (inflammation in parts of the large intestine) or ulcers in your stomach or intestines. Some people taking LEQSELVI can get tears in their stomach or intestines.
   - Call your healthcare provider or go to the nearest hospital emergency room right away if you have stomach-area pain, fever, chills, nausea or vomiting.
7. **Low blood sugar in people with diabetes.** If you have diabetes, your healthcare provider may instruct you to check your blood sugar levels more often during treatment with LEQSELVI. Call your healthcare provider if you have any problems with low blood sugar (hypoglycemia).
8. **Changes in certain laboratory test results.** Your healthcare provider should do blood tests before you start taking LEQSELVI and during treatment to check for the following:
   - **increased fat (lipid) levels in your blood (triglycerides and cholesterol).**
   - **low red blood cell counts**. This may mean that you have anemia, which may make you feel weak or tired.
   - **low lymphocyte or neutrophil counts**. Lymphocytes and neutrophils are white blood cells that help the body fight off infections.

   You should not take LEQSELVI if your white blood cell or red blood cell counts are too low. Your healthcare provider may stop your LEQSELVI treatment for period of time if needed because of changes in these blood test results.

See **"What are the possible side effects of LEQSELVI?"** for more information about side effects.

What is LEQSELVI?

LEQSELVI is a prescription medicine that is a Janus Kinase (JAK) inhibitor. LEQSELVI is used to treat adults with severe hair loss (alopecia areata).

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

Do not take LEQSELVI if you:

- are a poor metabolizer of CYP2C9 medicines. Before starting treatment with LEQSELVI, your healthcare provider should test you for CYP2C9 variants.
- take moderate or strong CYP2C9 inhibitor medicines. Ask your healthcare provider or pharmacist if you are not sure if you take any of these medicines.

Before taking LEQSELVI, tell your healthcare provider about all of your medical conditions, including if you:

- See **"What is the most important information I should know about LEQSELVI?"**
- have an infection.
- are a current or past smoker.
- have had a heart attack, or other heart problems or stroke.
- have had blood clots in your legs, lungs or brain.
- have kidney problems.
- have liver problems.
- have any stomach area (abdominal) pain or been diagnosed with diverticulitis or ulcers in your stomach or intestine.
- have diabetes.
- have low red or white blood cell counts.
- have recently received or are scheduled to receive a vaccine. People who take LEQSELVI should not receive live vaccines.

- are pregnant or plan to become pregnant. It is not known if LEQSELVI will harm an unborn baby. Tell your healthcare provider if you are pregnant or plan to become pregnant during treatment with LEQSELVI.
  - **Females who are able to become pregnant** should use effective birth control (contraception) during treatment with LEQSELVI. Talk to your healthcare provider about birth control methods that may be right for you during treatment with LEQSELVI.
  - If you become pregnant during treatment with LEQSELVI, call Sun Pharmaceuticals Industries, Inc at 1-800-818-4555 to report your pregnancy.
- are breastfeeding or plan to breastfeed. It is not known if LEQSELVI passes into your breastmilk. You should not breastfeed during treatment with LEQSELVI and for 1 day after the last dose. Talk to your healthcare provider about the best way to feed your baby during treatment with LEQSELVI.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. LEQSELVI and other medicines may affect each other causing side effects.

Especially tell your healthcare provider if you take medicines that affect your immune system such as biologic medicines, other JAK inhibitors, and strong immunosuppressants (such as cyclosporine) as these medicines may increase your risk of infection.

Ask your healthcare provider or pharmacist if you are not sure if you are taking one of these medicines.

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

How should I take LEQSELVI?

- Take LEQSELVI exactly as your healthcare provider tells you to take it.
- Take LEQSELVI 2 times a day with or without food.
- If you miss a dose of LEQSELVI, skip the missed dose and take the next dose at your regularly scheduled time.
- If you take too much LEQSELVI, call your healthcare provider or poison control center at 1-800-222-1222, or go to the nearest hospital emergency room right away.

What are the possible side effects of LEQSELVI?

LEQSELVI may cause serious side effects, including:

- See **"What is the most important information I should know about LEQSELVI?"**

The most common side effects of LEQSELVI include:

- headache
- acne
- pain or swelling of your nose or throat (nasopharyngitis)
- increased blood creatine phosphokinase
- increased blood cholesterol
- tiredness
- weight gain
- increased platelets in your blood (thrombocytosis)
- low red blood cell count (anemia)
- skin and soft tissue infections
- low white blood cell count (neutropenia)
- herpes simplex including cold sores

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

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 LEQSELVI?

- Store LEQSELVI at room temperature between 68°F to 77°F (20°C to 25°C).
- Store LEQSELVI in the original container to protect from moisture.
- LEQSELVI comes with a child-resistant cap.

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

General information about the safe and effective use of LEQSELVI.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use LEQSELVI for a condition for which it was not prescribed. Do not give LEQSELVI 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 LEQSELVI that is written for health professionals.

What are the ingredients in LEQELVI?

Active ingredient: deuruxolitinib

Inactive ingredients: colloidal silicon dioxide, lactose monohydrate, low-substituted hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose and povidone. The tablet film coat contains: carmine, FD&C blue #2 aluminum lake, glyceryl mono and dicaprylocaprate, polyvinyl alcohol, sodium lauryl sulfate, talc, and titanium dioxide.

Manufactured for Sun Pharmaceutical Industries, Inc. by Halo Pharmaceutical Inc., Whippany, NJ, 07981, USA.



This Medication Guide has been approved by the U.S. Food and Drug Administration. Issued: 06/2026