

Package leaflet: Information for the patient

Leqselvi 8 mg film-coated tablets deuruxolitinib

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Leqselvi is and what it is used for
2. What you need to know before you take Leqselvi
3. How to take Leqselvi
4. Possible side effects
5. How to store Leqselvi
6. Contents of the pack and other information

1. What Leqselvi is and what it is used for

Leqselvi contains the active substance deuruxolitinib. It is used to treat severe alopecia areata in adults. Alopecia areata is a disease where the body's own immune system attacks hair follicles, causing inflammation that leads to hair loss on the scalp, face and/or other parts of the body.

Leqselvi works by reducing the activity of enzymes called JAK1, JAK2 and TYK2 relative to JAK3 kinases, which are involved in inflammation at the hair follicle. This reduces the inflammation, leading to hair regrowth in patients with alopecia areata.

2. What you need to know before you take Leqselvi

Do not take Leqselvi

- if you are allergic to deuruxolitinib or any of the other ingredients of this medicine listed in section 6.
- if you have a serious infection ongoing, including tuberculosis.
- if you have severe liver problems.
- if you are pregnant or breast-feeding (see the "pregnancy, contraception, breast-feeding and fertility" section).

Warnings and precautions

Talk to your doctor or pharmacist before taking and during treatment with Leqselvi if you:

- Are older than 65. Patients aged 65 years and older may be at increased risk of infections, heart problems including heart attack and some types of cancer. Your doctor will discuss with you if Leqselvi is appropriate for you.
- have a chronic or recurrent infection or have a history of a serious or opportunistic infection

- have been exposed to tuberculosis or have resided or travelled in areas of endemic tuberculosis or endemic mycoses; or
- have underlying conditions that may predispose them to infection
- have viral reactivation, including cases of herpes virus reactivation (e.g., herpes zoster) or have ever had hepatitis B or hepatitis C
- have developed a cancer (other than successfully treated non-melanoma skin cancers)
- have cardiovascular risk factors
- are current or past smoker
- have had blood clots in an artery (thrombosis)
- have had lipid elevations (cholesterol), anaemia (not enough red blood cells), neutropenia (lower-than-normal levels of neutrophils, a type of white blood cell), and lymphopenia (few lymphocytes, white blood cells that protect you from infection)
- have recently had or plan to have a vaccination (immunization). Certain vaccines (live vaccines) are not recommended during or immediately prior to Leqselvi treatment

Prior to Leqselvi treatment, testing patients for CYP2C9 variants to determine if they are poor metabolizers is strongly recommended.

Children and adolescents

This medicine is not approved for use in paediatric population because the safety and benefits of Leqselvi have not been established in paediatric patients.

Other medicines and Leqselvi

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines to treat:

- infections (herpes, hepatitis B or hepatitis C),
- cancer,
- heart rhythm problems,
- headache.

Leqselvi may increase the amount of these medicines in your blood.

If any of the above apply to you or if you are not sure, talk to your doctor or pharmacist before taking Leqselvi.

Leqselvi can be taken with food and drinks.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Women of childbearing potential

If you are a woman of childbearing potential, you should use an effective method of contraception during treatment with Leqselvi. Your doctor can advise you on suitable methods of contraception.

Pregnancy

Do not use Leqselvi if you are pregnant, think you may be pregnant or are planning to have a baby. This medicine can harm the developing baby. Tell your doctor right away if you become pregnant or think you might have become pregnant during treatment.

Breast-feeding

Do not use Leqselvi while breast-feeding as it is not known if this medicine passes into breast milk. A risk to newborns/infants cannot be excluded. You and your doctor should decide if you will breast-feed or use this medicine.

Fertility

Based on animal studies, deuruxolitinib may cause foetal harm when administered during pregnancy. Consider pregnancy planning and prevention for women of reproductive potential.

Driving and using machines

No data are available on the ability to drive and use machines during Leqselvi treatment.

Leqselvi contains lactose

If you have rare hereditary problems of lactose intolerance, or sugar malabsorption, contact your doctor before taking this medicine.

3. How to take Leqselvi

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is 8 mg orally twice daily, with or without food.

Use in children and adolescents

This medicine is not recommended for children and adolescents.

If you take more Leqselvi than you should

If you take more Leqselvi than you should, contact your doctor. You may get some of the side effects described in section 4.

If you forget to take Leqselvi

Do not take a double dose to make up for a forgotten tablet, and resume dosing at the next scheduled dose.

If you stop taking Leqselvi

You should not stop taking Leqselvi without discussing this with your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Most serious side effects:

Tell your doctor or seek medical help immediately if you get the following symptoms, which may be signs of:

- shingles (herpes zoster): painful skin rash with blisters and fever (common)
- Pulmonary infections (e.g. COVID-19)
- Skin and soft tissue infections which include folliculitis, impetigo, skin infection, subcutaneous abscess, furuncle, paronychia, and pustule

Other side effects

Very common (may affect more than 1 in 10 people):

- Headache
- Acne

Common (may affect up to 1 in 10 people):

- Runny nose and sore throat (Nasopharyngitis)
- Skin infections
- Herpes
- Lipid elevations (cholesterol)
- Tiredness (asthenia, hypersomnia, somnolence, and lethargy)
- Blood creatine phosphokinase increased (enzyme shown by a blood test)
- Weight gain

Uncommon (may affect up to 1 in 100 people):

- Anaemia (decrease or low red blood cell count)
- Neutropenia (lower-than-normal levels of neutrophils, a type of white blood cell)
- Lymphopenia (few lymphocytes, white blood cells that protect you from infection)
- Thrombocytosis (high number of platelets)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Leqselvi

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage condition.

Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Leqselvi contains

- The active substance is deuruxolitinib. Each tablet contains 8 mg of deuruxolitinib (as phosphate).
- The other ingredients are the following:
 - Tablet core content:
 - Microcrystalline cellulose
 - Lactose monohydrate
 - Povidone K30 (E1201)
 - Low-substituted hydroxypropyl cellulose
 - Colloidal silicon dioxide
 - Magnesium stearate
 - Purified water
 - Film coating content:
 - Polyvinyl alcohol
 - Talc
 - Titanium dioxide
 - Glyceryl mono and dicaprylocaprate
 - Sodium lauryl sulfate

- Fd&c blue #2 aluminum lake
- Carmine
- Purified water

What Leqselvi looks like and contents of the pack

Leqselvi is a purple, round tablet of 6.5 mm diameter, debossed with “C” on one side and “8” on the other side.

Each high-density polyethylene (HDPE) bottle contains 60 film-coated tablets.

The bottle contains a silica gel desiccant used to keep the tablets dry. Do not swallow the silica gel desiccant.

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Blind or partially sighted?

Is this leaflet hard to see or read?

Call 0800 198 5000 to obtain the leaflet in a format suitable

This leaflet was last revised in February 2026.