A Proven New Option for People Living with Severe Alopecia Areata

LEQSELVI™ (deuruxolitinib) tablets 8mg

LEQSELVI™ (deuruxolitinib) 8 mg tablets is a new, twice-daily oral JAK inhibitor for the treatment of adult patients with severe alopecia areata.

In alopecia areata, the body does not recognize hair as part of the body and the immune system attacks it, making hair fall out. LEQSELVI treats hair loss at its source, targeting two important JAK proteins involved in hair loss, so hair can grow like it should.[1,2]

A New Oral Treatment Option with Proven Results

In clinical trials of LEQSELVI, one-third of people were able to get most of their hair back (80% or more hair coverage) by 24 weeks.[1]

People were more likely to get almost all their hair back (80% or more hair coverage) the longer they stayed on LEQSELVI.[1]

In placebo-controlled trials, the three most common adverse events were headache (12.4% as compared to 9.4% with placebo), acne (10% as compared to 4.3% with placebo), and nasopharyngitis (8.1% as compared to 6.7% with placebo). [1]

LEQSELVI may cause serious side effects including serious infections, malignancies, thrombosis, gastrointestinal perforations, and certain laboratory abnormalities. There also may be an increased risk of mortality and major cardiovascular events. LEQSELVI should not be used in patients who are CYP2C9 poor metabolizers or who are taking moderate or strong CYP2C9 inhibitors. See full Prescribing Information including BOXED WARNING and Medication Guide.

About Alopecia Areata

Alopecia areata affects around **700,000 people in the United States**, and **300,000 have severe alopecia areata.**[3,4]

LEQSELVI offers a new and effective option for those battling severe alopecia areata.

With AA, it's more than just hair. People dealing with severe alopecia areata experience serious psychological consequences, including anxiety and depression.[4]

Important Safety Information

Indications and Usage
LEQSELVI (deuruxolitinib) is a Janus kinase (JAK) inhibitor indicated for the treatment of adults with severe alopecia areata.

Limitations of Use
LEQSELVI is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine or other potent immunosuppressants.

Contraindications
LEQSELVI is contraindicated in patients who are CYP2C9 poor metabolizers or who are using moderate or strong CYP2C9 inhibitors.

Warnings

Serious Infections
Increased risk of serious bacterial, fungal, viral and opportunistic infections including tuberculosis (TB) that may lead to hospitalization or death. Interrupt treatment with LEQSELVI if a serious infection occurs until the infection is controlled. Test for latent TB before and during therapy; treat latent TB prior to use. Monitor all patients for active TB during treatment, even patients with initial negative, latent TB test.

Mortality
Higher rate of all-cause mortality, including sudden cardiovascular death with another Janus kinase inhibitor (JAK) vs. TNF blockers in rheumatoid arthritis (RA) patients. LEQSELVI is not approved for use in RA patients.

Malignancy
Malignancies have occurred in patients treated with LEQSELVI. Higher rate of lymphomas and lung cancers with another JAK inhibitor vs. TNF blockers in RA patients.

Major Adverse Cardiovascular Events
Higher rate of MACE (defined as cardiovascular death, myocardial infarction, and stroke) with another Janus kinase inhibitor (JAK) vs. TNF blockers in rheumatoid arthritis (RA) patients.

Thrombosis
Thrombosis, including PE, DVT & CVT, has occurred in patients treated with LEQSELVI. Increased incidence of pulmonary embolism, venous and arterial thrombosis with another JAK inhibitor vs. TNF blockers.

Increased risk of serious adverse reactions in CYP2C9 poor metabolizers or with concomitant use of moderate or strong CYP2C9 inhibitors
Do not treat patients who are CYP2C9 poor metabolizers or patients taking a moderate or strong CYP2C9 inhibitor with LEQSELVI.

Gastrointestinal Perforations
GI perforations have occurred in patients treated with LEQSELVI. Monitor patients who may be at increased risk for gastrointestinal perforation. Evaluate promptly patients presenting with new onset abdominal symptoms.

Lipid elevations, anemia, neutropenia, and lymphopenia
Monitor for changes in lipids, hemoglobin, neutrophils, and lymphocytes.

Immunizations
Avoid use of live vaccines during or immediately prior to LEQSELVI treatment. Prior to initiating LEQSELVI, it is recommended that patients be brought up to date with all immunizations.

Dosage
The recommended dosage of LEQSELVI for the treatment of severe alopecia areata is 8 mg orally twice daily, with or without food.

Before treatment with LEQSELVI, perform the following evaluations:
- CYP2C9 genotype & use of moderate or strong CYP2C9 inhibitors;
- Active and latent tuberculosis evaluation;
- Viral hepatitis screening;
- Complete blood count (LEQSELVI treatment is not recommended in patients with an absolute lymphocyte count (ALC) <500 cells/mm3 absolute neutrophil count (ANC) <1,000 cells/mm3, or hemoglobin level <8 g/dl).

Adverse Reactions
Most common adverse reactions (≥1%) are headache, acne, nasopharyngitis, blood creatine phosphokinase increased, hyperlipidemia, fatigue, weight increased, lymphopenia, thrombocytosis, anemia, skin and soft tissue infections, neutropenia, and herpes.

Use in Specific Populations
Based on animal studies, LEQSELVI may cause fetal harm during pregnancy. Pregnant women should be advised of a risk to the fetus. Consider pregnancy planning and prevention for women of reproductive potential. LEQSELVI should not be used by women who are breastfeeding until one day after the last dose.

LEQSELVI should not be used by patients with severe renal impairment or severe hepatic impairment.

To report SUSPECTED ADVERSE REACTIONS, contact Sun Pharmaceutical Industries, Inc. at 1-800-818-4555 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

To learn more about LEQSELVI, including full Prescribing Information, visit www.LEQSELVI.com

References: 1. LEQSELVI Prescribing Information. LEQSELVI U.S. Product Information. July 2024. Princeton, N.J.: Sun Pharmaceutical Industries Ltd **2.** Pratt H et al. Alopecia areata. *Nat Rev Dis Primers.* 2017; 3: 17011. **3.** National Alopecia Areata Foundation. National Alopecia Areata Foundation. https://www.naaf.org/. **4.** Cleveland Clinic. "Alopecia Areata." Cleveland Clinic. n.d. Web. 09 July 2024.

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