Ruxotor

Ruxolitinib Phosphate INN

Everest

COMPOSITION

RUXOTOR Cream: Each gram of cream contains Ruxolitinib Phosphate INN equivalent to Ruxolitinib 15 mg.

PHARMACOLOGY

Ruxolitinib, a Janus kinase (JAK) inhibitor, inhibits JAK1 and JAK2 which mediate the signaling of a number of cytokines and growth factors that are important for hematopoiesis and immune function. JAK signaling involves recruitment of STATs (signal transducers and activators of transcription) to cytokine receptors, activation and subsequent localization of STATs to the nucleus leading to modulation of gene expression. The relevance of inhibition of specific JAK enzymes to therapeutic effectiveness is not currently known.

Absorption

Plasma concentrations of Ruxolitinib were quantifiable in all subjects. There is no evidence of Ruxolitinib accumulation after daily application of Ruxolitinib for 28 days in subjects with atopic dermatitis.

Distribution

Plasma protein binding is approximately 97%.

Elimination

The mean terminal half-life of Ruxolitinib following topical application of Ruxolitinib is approximately 116 hours.

Metabolism

Ruxolitinib is primarily metabolized by CYP3A4 and to a lesser extent by CYP2C9 in vitro.

Excretion

Ruxolitinib and its metabolites are primarily excreted by urine (74%) and feces (22%). Less than 1% is excreted as unchanged drug.

INDICATION

Ruxolitinib is a Janus kinase (JAK) inhibitor, which is indicated for atopic dermatitis and vitiligo.

Atopic Dermatitis

Ruxolitinib is used in the topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adult and pediatric patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.

Vitiligo

Ruxolitinib is used in the topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older.

DOSE & ADMINISTRATION

Administration Instruction

Ruxolitinib cream should not use more than 60 gram per week or 100 gram per 2 weeks. It is for topical use only. It is not for intraocular, oral, or intravaginal use.

Recommended Dosage for Atopic Dermatitis

Patients should apply a thin layer of Ruxolitinib twice daily to affected areas of up to 20% body surface area. When signs and symptoms (e.g., itch, rash, and redness) of atopic dermatitis resolve it should be stopped. If signs and symptoms do not improve within 8 weeks, patients should be re-examined by registered doctor.

Recommended Dosage for Nonsegmental Vitiligo

Patients should apply a thin layer of Ruxolitinib twice daily to affected areas of up to 10% body surface area. Satisfactory patient response may require treatment with Ruxolitinib for more than 24 weeks. If the patient does not find the repigmentation meaningful by 24 weeks, the patient should be re-evaluated by registered doctor.

CONTRAINDICATION

It is contraindicated in patients with known hypersensitivity to Ruxolitinib or any other components of this product.

WARNING & PRECAUTION

Serious Infections

Use of Ruxolitinib should avoid in patients with an active, serious infection, including localized infections. If a serious infection develops, interrupt Ruxolitinib until the infection is controlled. The risks and benefits of treatment with Ruxolitinib should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection.

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Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with Ruxolitinib.

Mortality
In rheumatoid arthritis (RA) patients 50 years of age and older with at least one cardiovascular risk factor comparing an oral JAK inhibitor to tumor necrosis factor (TNF) blocker treatment, a higher rate of all-cause mortality, including sudden cardiovascular death, was observed with the JAK inhibitor.

Non-melanoma Skin Cancers
Non-melanoma skin cancers including basal cell and squamous cell carcinoma can be occurred in patients treated with Ruxolitinib. Periodic skin examinations should perform during Ruxolitinib treatment. Exposure to sunlight and UV light should be limited by wearing protective clothing and using broad-spectrum sunscreen.

Major Adverse Cardiovascular Events (MACE)
Patients who are current or past smokers are at additional increased risk of Major Adverse Cardiovascular Events. Patients who have experienced a myocardial infarction or stroke, Ruxolitinib should be discontinued.

Thrombosis
Thromboembolic events were observed in trials with Ruxolitinib. If symptoms of thrombosis occur, Ruxolitinib should be discontinued and treat appropriately.

Thrombocytopenia, Anemia, and Neutropenia
Thrombocytopenia, anemia, and neutropenia can be occurred. Perform CBC monitoring as clinically indicated.

SIDE EFFECTS
In atopic dermatitis, the most common side effects are nasopharyngitis, diarrhea, bronchitis, ear infection, eosinophil count increased, urticaria, folliculitis, tonsillitis, and rhinorrhea.

In nonsegmental vitiligo, the most common side effects are application site acne, application site pruritus, nasopharyngitis, headache, urinary tract infection, application site erythema, and pyrexia.

USE IN PREGNANCY AND LACTATION
Because of the serious adverse findings in adults, including risks of serious infections, thrombocytopenia, anemia, and neutropenia, women should not breastfeed during treatment with Ruxolitinib and for approximately four weeks after the last dose.

USE IN CHILDREN
The safety and effectiveness of Ruxolitinib in pediatric patients younger than 12 years of age with atopic dermatitis and nonsegmental vitiligo have not been established.

DRUG INTERACTION
Ruxolitinib is known to be a substrate for cytochrome P450 3A4 (CYP3A4). Inhibitors of CYP3A4 may increase Ruxolitinib systemic concentrations whereas inducers of CYP3A4 may decrease Ruxolitinib systemic concentrations.

Strong Inhibitors of CYP3A4
Concomitant use of Ruxolitinib should avoid with strong inhibitors of CYP3A4 as there is a potential to increase the systemic exposure of Ruxolitinib and could increase the risk of Ruxolitinib adverse reactions.

OVERDOSE
No data available.

PHARMACEUTICAL INFORMATION
Storage Condition
Store below 30°C in a dry place, away from sunlight & keep out of reach of children.

HOW SUPPLIED
RUXOTOR Cream: Each box contains 30 gm cream in a laminated tube.

Manufactured for
Everest Pharmaceuticals Ltd.
BSCIC I/A, Kanchpur, Narayanganj, Bangladesh
Manufactured by Sharif Pharmaceuticals Ltd.
Rupganj, Narayanganj, Bangladesh

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