Rutinib

Ruxolitinib INN 1.5% Cream

Composition : Each gram cream contains Ruxolitinib 15mg as Ruxolitinib Phosphate INN.

Pharmacology : Mechanism of Action: Janus kinase (JAK) pathways inhibitor; JAK consists of a group of intracellular tyrosine kinases that transmit signals from cytokine or growth factor-receptor interactions on the cellular membrane to influence cellular processes of hematopoiesis and immune cell function, including inflammation associated with atopic dermatitis. JAKs phosphorylate and recruit signal transducers and activators of transcription (STATs) which modulate intracellular activity including gene expression. JAK inhibitors modulate the JAK signaling pathway, which in turn prevents the phosphorylation and activation of STATs. **Absorption:** Peak plasma concentration: 449 nM (adults); 110 nM (adolescents). **AUC:** 3,215 h·nM (adults); 801 h·nM (adolescents). **Distribution:** Protein bound of Ruxolitinib is approximately 97%. **Metabolism:** Primarily metabolized by CYP3A4 and CYP2C9 (lesser extent) in vitro. **Half-life:** 116 hr. **Excretion:** Urine (74%) and feces (22%); <1% excreted as unchanged drug.

Indications : Atopic Dermatitis : Ruxolitinib is a Janus kinase (JAK) inhibitor indicated for the topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis (AD) in non-immunocompromised patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.

Dosage and administration : Apply thin layer of cream to affected areas BID of up to 20% body surface area; not to exceed >60 g/week. It should stop using when signs and symptoms (eg, itch, rash, redness) of atopic dermatitis resolve. If signs and symptoms do not improve within 8 weeks, re-examine patient. Or, as directed by the registered physician.

Contraindications : It is contraindicated in patients with known hypersensitivity to the drug or any of its components.

Precautions : Serious infections: i) Serious and sometimes fatal infections due to bacterial, mycobacterial, invasive fungal, viral, or other opportunistic pathogens reported with oral JAK inhibitors. **ii)** Serious lower respiratory tract infections reported in the clinical development program with topical Ruxolitinib. **Viral reactivation:** Viral reactivation, including cases of herpes virus reactivation (eg, herpes zoster), were reported with JAK inhibitors used to treat inflammatory conditions. **Hepatitis B and C: i)** Impact of JAK inhibitors used to treat inflammatory conditions on chronic viral hepatitis reactivation is unknown. **ii)** Patients with history of hepatitis B or C infection were excluded from clinical trials.

Side effects : Side effects of Ruxolitinib cream are Nasopharyngitis (3%), Bronchitis (1%), Ear infection (1%), Eosinophil count increased (1%), Urticaria (1%), Diarrhea (1%), Folliculitis (1%), Tonsillitis (1%), Rhinorrhea (1%).

Use in pregnancy and lactation : There is no data available.

Use in child : There is no data available.

Drug interactions :

I. Drug interaction studies were not conducted

II. Ruxolitinib is a substrate of CYP3A4

III. Strong CYP3A4 inhibitors

a. Avoid coadministration

b. Strong CYP3A4 inhibitors may increase ruxolitinib systemic exposure and adverse reactions

Overdose : There is no data available.

Storage : Store below 30°C away from sunlight and keep out of reach of children.

Packing : Each tube contains 30 gm cream.

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