Ruxonib Cream

Ruxolitinib Phosphate INN

Composition
Each gram 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.

Indication
Ruxolitinib is a (JAK) inhibitor indicated for
• 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.
• the topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older.

Dosage and Administration
For atopic dermatitis: Apply a thin layer of Ruxolitinib twice daily to affected areas of up to 20% body surface area. Stop using when signs and symptoms (e.g., itch, rash, and redness) of atopic dermatitis resolve.
For nonsegmental vitiligo: Apply a thin layer of Ruxolitinib twice daily to affected areas of up to 10% body surface area.

Contraindications
None

Precaution
Serious and sometimes fatal infections due to bacterial, mycobacterial, invasive fungal, viral, or other opportunistic pathogens have been reported in patients receiving oral JAK inhibitors. Serious lower respiratory tract infections were reported in the clinical development program with topical ruxolitinib.
Tuberculosis: No cases of active tuberculosis (TB) were reported in clinical trials with ruxolitinib.

Viral Reactivation: Viral reactivation, including cases of herpes virus reactivation (e.g., herpes zoster), were reported in clinical trials with Janus Kinase inhibitors used to treat inflammatory conditions including ruxolitinib.

Hepatitis B and C: Hepatitis B viral load (HBV-DNA titer) increases, with or without associated elevations in alanine aminotransferase and aspartate aminotransferase, have been reported in patients with chronic HBV infections taking oral ruxolitinib. Ruxolitinib initiation is not recommended in patients with active hepatitis B or hepatitis C.

Side Effects
In the treatment of atopic dermatitis: Neutropenia, allergic conjunctivitis, pyrexia, seasonal allergy, herpes zoster, otitis externa, staphylococcal infections, and acneiform dermatitis.
In the treatment of nonsegmental vitiligo: Application site dermatitis, hypertension, anxiety, application site discoloration, application site folliculitis, contusion, dermatitis contact, diarrhea, ear infection, gastritis, gastroenteritis, hordeolum, influenza-like illness, insomnia, nasal congestion, and vomiting.

Use in Pregnancy & Lactation:
Available data from pregnancies reported in clinical trials with ruxolitinib are not sufficient to evaluate a drug-associated risk for major birth defects, miscarriage, or other adverse maternal or fetal outcomes. There are no data on the presence of ruxolitinib in human milk, the effects on the breastfed child, or the effects on milk production.

Drug Interactions
Inhibitors of CYP3A4 may increase ruxolitinib systemic concentrations whereas inducers of CYP3A4 may decrease ruxolitinib systemic concentrations. Avoid concomitant use of ruxolitinib with strong inhibitors of CYP3A4 as there is a potential to increase the systemic exposure of ruxolitinib.

Overdose
There is no data available.

Storage
Do not store above 25º C. Protect from light. Keep out of the reach of children.

Packing
Each box contains a tube of 30g Cream.

Manufactured by:
ZISKA PHARMA **Ziska Pharmaceuticals Ltd.**
Kaliakoir, Gazipur, Bangladesh
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