Rofusis®

Roflumilast USP 0.3%

Description: Roflumilast is a phosphodiesterase 4 inhibitor which is used to treat plaque psoriasis.

Mode of action: Roflumilast and its active metabolite (roflumilast N-oxide) are inhibitors of PDE4. Roflumilast and roflumilast N-oxide inhibition of PDE4 activity leads to accumulation of intracellular cyclic AMP. The specific mechanism(s) by which roflumilast exerts its therapeutic action is not well defined.

Pharmacokinetics: Plasma concentrations of roflumilast and roflumilast N-oxide (see Metabolism) were quantifiable. After application of roflumilast, the plasma concentration versus time profile was relatively flat, generally with a peak-to-trough ratio less than 2. Plasma protein binding of roflumilast and its N-oxide metabolite is approximately 99% and 97%, respectively. Roflumilast is extensively metabolized via Phase I (cytochrome P450) and Phase II (conjugation) reactions. The N-oxide metabolite is the only major metabolite observed in the plasma of humans. Following topical administration, the half-lives of roflumilast and the N-oxide metabolite were 4.0 and 4.6 days, respectively.

Composition: Each gm contains Roflumilast USP 3 mg.

Indication: Indicated for topical treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older.

Dosage & administration:
Apply once daily to affected areas.
• For topical use only.
• Not for ophthalmic, oral, or intravaginal use.

Contraindications: Moderate to severe liver impairment (Child-Pugh B or C).

Side effects: The most common side effects are diarrhea, headache, trouble sleeping, nausea etc.

Use in pregnancy & lactation: There are no randomized clinical trials of oral or topical roflumilast in pregnant women. In animal reproduction studies, roflumilast administered orally to pregnant rats and rabbits during the period of organogenesis produced no fetal structural abnormalities at doses up to 9 and 8 times the maximum recommended human dose (MRHD), respectively. The background risk of major birth defects and miscarriage for the indicated population is unknown.
There is no information regarding the presence of roflumilast in human milk, the effects on the breastfed infant, or the effects on milk production.

Precautions: Roflumilast may not be given if patients have liver problems, previous allergic reaction to this or a similar drug, pregnancy, breastfeeding etc.

Drug interactions: Oral Roflumilast may interact with erythromycin, ketoconazole, fluvoxamine, enoxacin, cimetidine etc.

Over dosage: No data found.

Storage: Keep out of reach of children. Store in a dry place, below 25˚C temperature and protected from light.

Packaging: Rofusis® Cream: Each carton contains 30 gm cream in lami tube.

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Opsonin Pharma
Ideas for healthcare

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