

Doxiderm®

Doxepin Hydrochloride 5% cream

Presentation

Doxiderm® Cream: Each gram cream contains Doxepin Hydrochloride USP 50 mg.

Description

Doxepin Hydrochloride is one of a class of agents known as dibenzoxepin tricyclic antidepressant compounds. Although Doxepin Hydrochloride does have H1 and H2 histamine receptor blocking actions, the exact mechanism by which doxepin exerts its antipruritic effect is unknown. It can produce drowsiness in significant numbers of patients, and this sedation may reduce awareness, including awareness of pruritic symptoms.

Indications

Doxiderm cream is indicated for the short-term (upto 8 days) management of moderate pruritus in adult patients with atopic dermatitis or lichen simplex chronicus.

Dosage and Administration

Adult and child over 12 years: apply thinly 3-4 times daily; usual max. 3 g per application; usual total max. 12 g daily; coverage should be less than 10% of body surface area.

Side effects

Drowsiness, local burning, stinging, irritation, tingling, rash; systemic side-effects such as antimuscarinic effects, headache, fever, dizziness, gastro-intestinal disturbances has been reported.

Precautions

Cautions should be exercised if there is susceptibility to angle-closure glaucoma, urinary retention, severe liver impairment, mania and also in pregnancy and breast-feeding. Drowsiness may affect performance of skilled tasks (e.g. driving) so patient should be careful.

Use in Pregnancy and Lactation

Pregnancy: Category B-There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy only if clearly needed.

Nursing Mothers: Doxepin is excreted in human milk after oral administration. It is possible that doxepin may also be excreted in human milk following topical application of Doxiderm cream.

Use in Children

The use of Doxiderm cream in pediatric patients is not recommended. Safe conditions for use of cream in children have not been established.

Use in Elderly Patients

Dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy.

Contraindications

- Patients with untreated narrow angle glaucoma or a tendency to urinary retention because Doxepin Hydrochloride has an anticholinergic effect
- Individuals who have shown previous sensitivity to any of its components

Drug Interactions

Concomitant use of tricyclic antidepressants with drugs that can inhibit cytochrome P450 2D6 like MAO inhibitors, cimetidine, alcohol may require lower doses than usually prescribed for either the tricyclic antidepressant or the other drug. MAO inhibitors should be discontinued at least two weeks prior to the cautious initiation of therapy with Doxiderm cream.

Overdosage

If overdosage with topical application of Doxiderm cream occur, the signs and symptoms may include cardiac dysrhythmias, severe hypotension, convulsions, and CNS depression, including coma. Changes in the electrocardiogram, particularly in QRS axis or width, are clinically significant indicators of tricyclic antidepressant toxicity. Other signs of overdose may include confusion, disturbed concentration, transient visual hallucinations, dilated pupils, agitation, hyperactive reflexes, stupor, drowsiness, muscle rigidity, vomiting, hypothermia, hyperpyrexia.

Commercial Pack

Doxiderm® Cream: Tube containing 30 gm of Doxepin Hydrochloride cream.

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 **Incepta Pharmaceuticals Ltd**
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