

Apsol[®]

Amlexanox 5% Oral Paste

COMPOSITION

Each gram of oral paste contains 50 mg of Amlexanox INN.

PHARMACOLOGY

The mechanism of action by which Amlexanox accelerates healing of aphthous ulcers is unknown. In vitro studies have demonstrated Amlexanox to be a potent inhibitor of the formation and release of inflammatory mediators (histamine and leukotrienes) from mast cells, neutrophils and mononuclear cells. Given orally to animals, Amlexanox has demonstrated anti-allergic and anti-inflammatory activities and has been shown to suppress both immediate and delayed type hypersensitivity reactions. The relevance of these activities of Amlexanox to its effects on aphthous ulcers has not been established. After a single oral application of 100 mg of paste (5 mg Amlexanox), maximal serum levels are observed at 2.4 hours. Most of the systemic absorption of Amlexanox is via the gastrointestinal tract and the amount absorbed directly through the active ulcer is not a significant portion of the applied dose. The half-life for elimination was 3.5 +/- 1.1 hours in healthy individuals.

INDICATIONS

For the treatment of aphthous ulcers.

DOSAGE & ADMINISTRATION

- Apply the paste as soon as possible after noticing the symptoms of an aphthous ulcer. Continue to use the paste four times daily, preferably following oral hygiene after breakfast, lunch, dinner, and at bedtime.
- Dry the ulcer(s) by gently patting it with a soft, clean cloth.
- Wash hands before applying.
- Moisten the tip of the index finger.
- Squeeze a dab of paste approximately 1/4 inch (0.5 cm) on to a finger tip.
- Gently dab the paste on to the ulcer. Repeat the process if more than one ulcer are present.
- Wash hands after application.
- Wash eyes promptly if they should come in contact with the paste.
- Use the paste until the ulcer heals. If significant healing or pain relief has not occurred in 10 days, consultation with the physician is required.

ADVERSE EFFECTS

Adverse reactions reported by 1-2% of patients were transient pain, stinging and/or burning at the site of application. Infrequent (<1%) adverse reactions in the clinical studies were contact mucositis, nausea, and diarrhea.

CONTRAINDICATION

Amlexanox oral paste is contraindicated in patients with known hypersensitivity to Amlexanox or other ingredients in the formulation.

PRECAUTION & WARNING

Wash hands immediately after applying Amlexanox oral paste directly to ulcers with the finger tips. In the event that a rash or contact mucositis occurs, discontinue use.

USE IN SPECIAL POPULATION

Pregnancy: US FDA pregnancy category B. Teratology studies were performed with animals at doses up to two hundred and six hundred times, respectively, the projected human daily dose. No adverse fetal effects were observed. There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers: Amlexanox was found in the milk of lactating rats; therefore, caution should be exercised when administering Amlexanox oral paste to a nursing woman.

Pediatric Use: Safety and effectiveness of Amlexanox oral paste in pediatric patients have not been established.

OVERDOSE

Ingestion of a full tube of 5 grams of paste would result in systemic exposure well below the maximum nontoxic dose of Amlexanox in animals. Gastrointestinal upset such as diarrhea and vomiting could result from an overdose.

STORAGE

Store in a cool & dry place, protected from light. Keep all medicines out of reach of the children.

HOW SUPPLIED

Apsol[®] Oral Paste: Tube containing 5 gm oral paste.

Manufactured by:



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH

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