

# Apsol<sup>®</sup> Oral Paste

Amlexanox 5%

## COMPOSITION:

**Apsol<sup>®</sup> Oral Paste:** Each gram of oral paste contains 50 mg 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.

## INDICATIONS:

For the treatment of Aphthous ulcers.

## DOSAGE & ADMINISTRATION:

Apply the paste as soon as possible after noticing the symptoms of an aphthous ulcer. Use four times daily, preferably following oral hygiene after breakfast, lunch, dinner, and at bedtime.

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:

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:** 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:** 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 at a cool & dry place, protected from light. Keep all medicines out of reach of the children.

## HOW SUPPLIED:

**Apsol<sup>®</sup> Oral Paste:** Tube containing 5 gm oral paste.

Manufactured by



**SQUARE**  
PHARMACEUTICALS LTD.  
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