

Composition : Each gram oral paste contains Amlexanox INN 50 mg.

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.

Indications : For the treatment of Aphthous ulcers.

Dosage & Administration :

1. 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, Moisture the tip of the index finger.
2. Squeeze a dab of paste approximately 1/4 inch (0.5 cm) on to a finger tip.
3. Gently dab the paste on to the ulcer. Repeat the process if more than one ulcer.□
 1. Wash hands when done applying. Wash eyes promptly if they should come in contact with the paste.
5. 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. Or, as directed by the registered physician.

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

Rupsol
Oral Paste



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.

Side 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 diarrhoea.

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. Amlexanox was found in the milk of lactating rats; therefore caution exercised when administering Amlexanox oral paste to a nursing woman.

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

Drug Interactions : There are no known drug interactions with this oral paste.

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 diarrhoea and vomiting could result from an overdose.

Storage : Store below 30° C away from sunlight, dry & cool place. Keep the medicine out of reach of the children.

Packing : Tube containing 5 gm oral paste.