

Amlex[®]

Amlexanox INN 5% w/w

Description:

Amlex[®] is an oral paste preparation of Amlexanox that exhibits both anti-allergic & anti-inflammatory properties. 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. Upon oral administration Amlexanox 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 of approximately 120 ng/ml 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. Approximately 17% of the dose is eliminated in the urine as unchanged Amlexanox, a hydroxylated metabolite and their conjugates. With multiple application four times daily steady state levels were reached within one week and no accumulation was observed with up to four weeks of usage.

Indication:

Amlex[®] is indicated for the treatment of aphthous ulcers in people with normal immune system.

Dosage and administration:

Adults (over 18 years of age): 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 ¼ inch (0.5 cm) on to the finger tip. Gently dab the paste on to each ulcer. Repeat the process if more than one ulcer are present. Wash hands after application. 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.

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

Use in pregnancy & lactation:

Pregnancy: Pregnancy category B. No adverse fetal effects were observed during teratological studies on animals, but there are no adequate and well-controlled studies in pregnant women. So this drug should be used during pregnancy only if clearly needed.

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

Side effects:

The most common side effects are transient pain, stinging and/or burning at the site of application. The less frequent side effects are contact mucositis, nausea, and diarrhea.

Precautions:

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

Contraindications:

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

Overdose:

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

Pharmaceutical Precaution:

Store in a cool & dry place. Protect from light. Keep out of reach of the children.

Presentation:

Amlex[®] Oral paste: Each gram of oral paste contains 50 mg of Amlexanox INN.

Packaging:

Amlex[®] Oral paste: Tube of 5g.

® Registered Trade Mark



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