

# Sorex<sup>®</sup>

Amlexanox INN Oral Paste

## DESCRIPTION

**Sorex<sup>®</sup>** oral paste is a preparation of Amlexanox. The mechanism of Amlexanox by which it accelerates healing of aphthous ulcers is unknown. In vitro studies have demonstrated Amlexanox to be a potent inhibitor of the formation and/or release of inflammatory mediators (histamine and leukotrienes) from mast cells, neutrophils and mononuclear cells.

## INDICATION

**Sorex<sup>®</sup>** oral paste is indicated for the treatment of aphthous ulcers in adults and adolescents 12 years of age and older. It is not indicated for use on children below 12 years or in patients with an abnormal immune system.

## DOSAGE AND ADMINISTRATION

**Sorex<sup>®</sup>** oral paste should be applied as soon as possible after noticing the symptoms of an aphthous ulcer and should be used 4 times daily, preferably following oral hygiene after breakfast, lunch, dinner and 80 minutes before bedtime. (Up to 3 patches may be used at one time. Apply 1 patch to each ulcer. Use of the medication should be continued until the ulcer heals but no longer than 10 days.) If significant healing or pain reduction has not occurred in 10 days, consult your dentist or physician.

## CONTRAINDICATION

**Sorex<sup>®</sup>** oral paste is contraindicated in patients with known hypersensitivity to Amlexanox.

## SIDE EFFECTS

Common local side effects are pain, burning, irritation and paresthesia at the site of the application. Other systemic side effects are nausea, vomiting, headache etc.

## PRECAUTIONS

Wash hands immediately after applying **Sorex<sup>®</sup>** oral paste directly to ulcers with the fingertips. In the event that a rash or contact dermatitis occurs, discontinue use.

## USE IN PREGNANCY AND LACTATION

Amlexanox is a drug of pregnancy category B so it can be used in pregnancy only if clearly needed. Amlexanox was found in milk therefore, caution should be exercised in administering it to a nursing mother.

## DRUG INTERACTION

There are no specific drug interactions with Amlexanox.

## PHARMACEUTICAL PRECAUTION

Do not store above 30 °C temperature. Keep away from light and wet place. Keep out of reach of children.

## PACKAGING

**Sorex<sup>®</sup>** oral paste: Tube containing 5 g of oral paste. Each gram oral paste contains Amlexanox INN 50 mg.

## SK+F

Manufactured by

**ESKAYEF PHARMACEUTICALS LTD.**

TONGI, GAZIPUR, BANGLADESH

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