

FESIN CAPSULES 200MG

NAME AND STRENGTH OF ACTIVE INGREDIENT(S):

Each capsule contains:

Guaifenesin.....200mg

The source of gelatin for empty gelatin capsule is of bovine origin.

PRODUCT DESCRIPTION:

A white or slightly off-white powder filled in size no. 1 capsules with opaque ivory cap and opaque ivory body.

PHARMACODYNAMICS:

Guaifenesin is an expectorant which is thought to act by irritating the gastric mucosa and subsequently stimulating respiratory tract secretions. This increase in fluid increases the volume and decreases the viscosity of bronchial secretions.

PHARMACOKINETICS:

Guaifenesin is well absorbed from the gastrointestinal tract. It is metabolised and then excreted in the urine. The half-life in plasma is approximately 1 hour.

INDICATION:

- Helps loosen phlegm and thin bronchial secretions.
- Symptomatic relief of chesty coughs.
- Expectorant for productive cough.

RECOMMENDED DOSAGE:

Adults and children 12 years and older: 200 - 400 mg every 4 hours, not to exceed 2400 mg in 24 hours.

ROUTE OF ADMINISTRATION:

Oral

CONTRAINDICATIONS:

Hypersensitivity to guaifenesin products.

WARNINGS AND PRECAUTIONS:

If symptoms persists, consult the doctor.

INTERACTIONS WITH OTHER MEDICAMENTS:***Diagnostic Interference:***

Guaifenesin has been shown to produce a colour interference with certain clinical laboratory determinations of 5-hydroxyindoleacetic acid (5-HIAA) and vanilmandelic acid (VMA).

Guaifenesin could interfere with the diagnosis of carcinoid syndrome. Patients being evaluated for carcinoid syndrome should therefore discontinue any preparation containing guaifenesin for 24 hours before collection of urine specimens for the determination of 5-hydroxyindoleacetic acid (5-HIAA).

STATEMENT ON USAGE DURING PREGNANCY AND LACTATION:

Available evidence and/or expert consensus is inconclusive or is inadequate for determining infant risk when used during pregnancy and breastfeeding. Weigh the potential benefits of drug treatment against potential risks before taking this drug during pregnancy and breastfeeding.

ADVERSE EFFECTS/ UNDESIRABLE EFFECTS:

Gastrointestinal discomfort, nausea and vomiting have occasionally been reported with guaifenesin, particularly in very large doses. Others include dizziness, diarrhoea, headache and rash (including urticaria).

OVERDOSE AND TREATMENT:

Nausea and vomiting may occur.

In the event of overdosage, discontinue medication and seek medical help immediately.

DOSAGE FORMS AND PACKAGING AVAILABLE:

Dosage Form: Capsule

Packing Size: Blister Pack: 50 x10's

NAME AND ADDRESS OF MANUFACTURER / PRODUCT REGISTRATION HOLDER:

MALAYSIAN PHARMACEUTICAL INDUSTRIES SDN BHD (101323-U)

Plot 14, Lebuhraya Kampung Jawa, 11900 Bayan Lepas,

Pulau Pinang, Malaysia.

DATE OF REVISION:

08/02/2022