PACKAGE INSERT TEMPLATE FOR GUAIFENESIN (GUAIPHENESIN/ Guaicol Glycerol Ether) TABLET/CAPSULE/SYRUP

Brand or Product Name

[Product name] Dosage Form, Strength

Name and Strength of Active Substance(s)

Guaifenesin …… mg or % w/v

Product Description

[Visual description of the appearance of the product (eg colour, shape etc)
eg Black, round tablets, flat on both sides

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.

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Recommended Dosage

a) LIQUID, SYRUP
-The recommended dose for adults and children 12 years and older is 200 to 400 milligrams every 4 hours, not to exceed 2400 milligrams in 24 hours
For maximum effectiveness, adequate fluid intake must be maintained when using guaifenesin as an expectorant.

b) TABLETS, IMMEDIATE-RELEASE
-The recommended dose for adults and children 12 years and older is 200 to 400 milligrams every 4 hours, not to exceed 2400 milligrams in 24 hours.

c) TABLETS, SUSTAINED-RELEASE
1) The recommended dose of sustained-release guaifenesin for adults and children over 12 years of age is 600 to 1200 milligrams every 12 hours, not to exceed 2400 milligrams in 24 hours

Paediatrics Dose
1) The following recommendations are for paediatric patients:
children 6 years to under 12 years - 100 to 200 milligrams every 4 hours, not to exceed 1200 mg in 24 hours;
children 2 years to under 6 years - 50 to 100 mg every 4 hours, not to exceed 600 mg in 24 hours
2) For children under 2 years of age, consult a physician; the dose should be individualized
A common dosage is 25 to 50 milligrams every 4 hours, not to exceed 300 mg in 24 hours

Mode of Administration

Oral

Contraindications

Hypersensitivity to guaifenesin products

Warnings and Precautions

If symptoms persists, consult the doctor.

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Interactions with Other Medicaments

Diagnostic Interference:

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

Guaiphenesin could intefere with the diagnosis of carcinoid syndrome. Patients being evaluated for carcinoid syndrome should therefore discontinue any preparation containing guaphenesin for 24 hours before collection of urine specimens for the determination of 5-hydroxy indole acetic 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.

Storage Conditions

[eg Store below….° C]

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Dosage Forms and Packaging Available

[Packaging type & pack size]

Name and Address of Manufacturer

[Name & full address of manufacturer]

Name and Address of Marketing Authorization Holder

[Name & full address of marketing authorization holder]

Date of Revision of Package Insert

[day/month/year]

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