

CORE GUAIPHENESIN PRODUCT INFORMATION

Product description

This section should include:

- a description of the dosage form;
- a list of the active ingredients expressed quantitatively; and
- a list of the excipients expressed qualitatively

Pharmacology

Pharmacokinetics:

Guaiphenesin is well absorbed from the gastrointestinal tract. It is metabolised primarily to Beta-2-methoxyphenoxy-lactic acid and then excreted in the urine. In a study where subjects were given 400mg of guaiphenesin orally, no unchanged drug could be detected in the urine. The plasma half life of guaiphenesin is one hour.

Pharmacodynamics/Mechanism of action:

Guaiphenesin is an expectorant which clears chest congestion by loosening and reducing the viscosity of phlegm, increasing the volume of phlegm and making coughs more productive.

Indications

This section must contain the indications of the product as specified in the ARTG. If the indications are not specified in the ARTG (e.g. for a non-validated grandfathered product), the indications must be as specified on the product label.

Contraindications

Guaiphenesin is contraindicated for use in persons with known hypersensitivity or idiosyncratic reaction to guaiphenesin (or any of the other ingredients in the product).

Precautions

Guaiphenesin is possibly porphyrogenic and should be used with caution in patients with porphyria.

Guaiphenesin should not be used for chronic or persistent cough associated with chronic lower respiratory tract diseases such as asthma, bronchitis, chronic obstructive pulmonary disease (COPD), emphysema or smoker's cough.

Use in pregnancy

Category A: Guaiphenesin has been taken by a large number of pregnant women and women of child bearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the foetus having been observed.

Lactation

It is not known whether guaiphenesin is excreted in breast milk or whether it has a harmful effect on the breastfeeding infant. Therefore it is not recommended for breastfeeding mothers unless the potential benefits to the patient are weighed against the possible risk to the infant.

Interaction with other medicines

There are no reported interactions with other medicines.

Adverse reactions

Guaiphenesin is generally well tolerated, but its side effects may include nausea, vomiting, dizziness, headache, rash, diarrhoea, drowsiness and stomach pain, particularly in very large doses.

Dosage

This section must contain the current dosage instructions of the registered product, as specified on the product label.

Overdosage

In case of overdose, immediately contact the Poisons Information Centre (in Australia, call 13 11 26; in New Zealand call 0800 764 766) for advice.

Presentation

Information should be included on:

- *the presentation, including dosage form and pack sizes;*
- *identifying details (eg. colour, shape, identifying markings);*
- *poisons schedule details; and*
- *name and address of the sponsor.*

Include the date of approval as the date on which the notification application is lodged