

NEW ZEALAND DATA SHEET

MUCINEX

Mucinex 600 mg modified-release tablets.

MAXIMUM STRENGTH MUCINEX

Mucinex 1200 mg modified-release tablets.

PRESENTATION

Modified-release tablet.

Blue/white bi-layered, oval, tablets with “600” on white immediate release layer and “Mucinex” on blue sustained release layer.

Blue/white bi-layered, oval, tablets with “1200” on white immediate release layer and “Mucinex” on blue sustained release layer.

INDICATIONS

Helps loosen phlegm and thin bronchial secretions.

Symptomatic relief of deep chesty coughs.
Expectorant for productive cough.

DOSAGE AND ADMINISTRATION

For oral use.

Adults and children 12 years and over:

Mucinex 600mg tablets

One to Two tablets to be taken with water every 12 hours.
Do not exceed four tablets in 24 hours.

Maximum Strength Mucinex 1200mg tablets

One tablet to be taken with water every 12 hours.
Do not exceed two tablets in 24 hours.

The tablet should not be chewed because this will affect the modified-release characteristics of the tablet.

Children under 12: Do not use.

Elderly: no changes to the posology scheme are required.

CONTRAINDICATIONS

Hypersensitivity (allergy) to the active substance or to any of the ingredients.

WARNINGS AND PRECAUTIONS

Special warnings and special precautions for use

If symptoms persist or no improvements are observed, do not exceed the recommended dose. Seek medical advice.

Patients suffering from the following should not take Mucinex® except on medical advice:- asthma, bronchitis, chronic obstructive pulmonary disease (COPD), emphysema, smoker's cough, porphyria.

Use in pregnancy and lactation

As with all medicines, if pregnant or breast feeding, seek medical advice before taking this product. There have been no adequate and well-controlled studies in pregnant women.

Effect on ability to drive and to use machines

Mucinex has no influence on the ability to drive and use machines

INTERACTIONS

Guaifenesin may increase the rate of absorption of paracetamol.

Guaifenesin may interfere with some diagnostic measurements (urinary 5-hydroxy-indoleacetic acid or vanillylmandelic acid).

ADVERSE EFFECTS

Guaifenesin has occasionally been reported to cause gastrointestinal (stomach) discomfort, nausea and vomiting, particularly in high doses.

Kidney stones have been reported in patients seeking to abuse the sympathomimetic (decongestant) or opiate component of combination products; which resulted in them taking large doses of Guaifenesin for long periods of time; doses up to 24 g per day have been reported.

The development of kidney stones in single active preparations of Guaiphenesin like Mucinex is extremely rare.

Guaiphenesin is rapidly metabolised and excreted in the urine.

OVERDOSE

Overdose with Guaifenesin is unlikely to produce toxic effects since its toxicity is low. Very large doses may cause nausea and vomiting. Guaiphenesin is, however, rapidly metabolised and excreted in the urine. Patients should be kept under observation and treated symptomatically.

FURTHER INFORMATION

Pharmacodynamic properties

ATC code: R05 CA03.

Guaifenesin is an expectorant which increases the volume of mucus that can be expelled or cleared by mucocilliary action due to reduction in the adhesiveness and viscosity of tenacious sputum.

Pharmacokinetic properties

Guaifenesin is readily absorbed from the gastrointestinal tract after oral administration and rapidly metabolised by oxidation to β -(2-methoxyphenoxy)-lactic acid. Approximately 40% of a dose is excreted as this metabolite in the urine within 3 hours. The half-life in plasma is approximately 1 hour.

600mg modified release Guaifenesin tablet administered every 12 hours has clearly been shown to be equivalent in exposure (as assessed by AUC) and in maximum concentration (as assessed by C_{max}) as that produced by 400mg immediate release Guaifenesin given every 4 hours

Preclinical safety data

No pre-clinical findings of relevance to the prescriber have been reported. Animal studies to assess the long-term carcinogenic and mutagenic potential or the effect on fertility in animals or humans have not been performed.

PHARMACEUTICAL PRECAUTIONS

List of excipients

Microcrystalline cellulose
Sodium starch glycollate
Hypromellose
Carbomer
Brilliant Blue FCF (E133)
Magnesium stearate

Incompatibilities

Not applicable

Shelf-life

3 years.

Special precautions for storage

Do not store above 25°C.

PACKAGE QUANTITIES

Pack sizes:

- 600mg tablets: 10, 20 tablets
- 1200mg tablets: 14 tablets (Not Marketed)

Polyvinyl chloride (PVC)/ polychlorotrifluoroethylene (PCTFE) blister strips, with a foil/paper laminate, enclosed in a cardboard carton.

Medicine Classification

General Sales:

Up to 40 600mg modified release tablets

Up to 20 1200mg modified release tablets

Pharmacist Only Medicine:

41 – 120 600mg modified release tablets

21 – 60 1200mg modified release tablets

SPONSOR DETAILS

Reckitt Benckiser (New Zealand) Limited,
Private Bag 93121

Henderson 0650

Auckland, New Zealand

Freephone: 0508 731 234

DATE OF PREPARATION

16 September 2011