NEW ZEALAND DATA SHEET

MUCINEX & MAXIMUM STRENGTH MUCINEX
Guaiphenesin 600 mg and 1200 mg modified-release tablets.

Presentation

**Mucinex 600 mg modified release tablet**: Blue/white bi-layered, oval, tablets imprinted with “600” on white immediate release layer and “Mucinex” on blue sustained release layer.

**Maximum Strength Mucinex 1200 mg modified release tablet**: Blue/white bi-layered, oval, tablets imprinted 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

**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 Guaiphenesin or to any of the ingredients listed under Further Information.

Do not take if suffering from porphyria.

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 with caution in patients with renal impairment.

Not recommended for concomitant use with a cough suppressant.

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.

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.

### Interactions

Guaifenesin may increase the rate of absorption of paracetamol.

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

### Overdosage

Overdose with Guaifenesin is unlikely to produce toxic effects since its toxicity is low. Symptoms associated with guaiphenesin overdose include headache, dizziness, nausea and vomiting. Extremely high doses may depress the central nervous system and act as a muscle relaxant. Prolonged use of guaiphenesin may result in urolithiasis. Guaiphenesin is however rapidly metabolised and excreted in the urine. Patients should be kept under observation and treated symptomatically.

### Pharmaceutical Precautions

**Incompatibilities**

Not applicable

**Shelf-life**

3 years.

**Special precautions for storage**

Do not store above 25°C.

### Medicine Classification

General Sales Medicine when packed in:

Up to 40 units of 600mg modified release tablets
Up to 20 units of 1200mg modified release tablets
Pharmacist Only Medicine when packed in:
41 to 120 units of 600 mg modified release tablets
21 to 60 units of 1200 mg modified release tablets

Package Quantities

Pack sizes:
General Sale Medicine
- 600mg tablets: 10, 20 & 40 tablets
- 1200mg tablets: 7, 14 & 20 tablets
Not all pack sizes are marketed.
Pharmacist Only (Restricted - Not marketed)
- 600mg tablets: 41, 60 & 100 tablets
- 1200mg tablets: 21 & 28 tablets

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

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 mucociliary 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.

List of excipients
Microcrystalline cellulose
Sodium starch glycollate
Hypromellose
Carbomer
Brilliant Blue FCF (E133)
Magnesium stearate
Name and Address

Reckitt Benckiser (New Zealand) Limited,
Private Bag 93523
Takapuna 0740
Auckland, New Zealand

Date of Preparation

17 August 2016