NEW ZEALAND DATA SHEET

Mucinex and Maximum Strength Mucinex

1. Product Name

Mucinex and Maximum Strength Mucinex

2. Qualitative and Quantitative Composition

Mucinex: Each modified release tablet contains 600 mg guaifenesin.

Maximum Strength Mucinex: each modified release tablet contains 1200 mg guaifenesin.

For a full list of excipients see Section 6.1.

3. Pharmaceutical Form

Mucinex: A blue and white bilayered, oval tablet imprinted with '600' on the white immediate release layer and 'Mucinex' on the blue sustained release layer.

Maximum Strength Mucinex: A blue and white bilayered, oval tablet imprinted with '1200' on the white immediate release layer and 'Mucinex' on the blue sustained release layer.

4. Clinical Particulars

4.1 Therapeutic Indications

Helps loosen phlegm and thin bronchial secretions.

Symptomatic relief of deep chesty cough

Expectorant for productive cough.

4.2 Posology and method of administration

Adults and children over 12 years

Mucinex 600 mg tablets

One to two tablets to be taken with water every 12 hours.

Do not exceed FOUR tablets in 24 hours.

Maximum Strength Mucinex 1200 mg tablets

One tablets 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 years

Do not use.

Elderly

No dosage adjustment is considered necessary in the elderly.

4.3 Contraindications

Hypersensitivity to guaifenesin or to any of the excipients in the product.

4.4 Special warnings and precautions for use

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

Seek medical advice if suffering from chronic cough or asthma, bronchitis, emphysema, chronic obstructive pulmonary disease (COPD) or smoker's cough.

Use in caution in patients with renal impairment.

Not recommended for concomitant use with a cough suppressant.

Do not take if you are pregnant or breast feeding unless recommended by a health care professional (see section 4.6)

Use with caution in patients suffering from porphyria.

4.5 Interactions with other medicinal products and other forms of interactions

Laboratory interference: If urine is collected within 24 hours of a dose of the medicinal product, a metabolite of guaifenesin may cause a colour interference with laboratory determinations of urinary 5-hydroxyindoleacetic acid (5-HIAA) and vanillylmandelic acid (VMA).

Guaifenesin may increase the rate of absorption of paracetamol.

4.6 Fertility, pregnancy and lactation

Pregnancy

A moderate amount of data on pregnant women (between 300 – 1000 pregnancy outcomes) indicate no malformative or feto/natal toxicity of guaifenesin.

As a precautionary measure, it is preferable to avoid use of the product during pregnancy.

Breast-feeding

The product should be avoided during lactation unless recommended by a healthcare professional.

There is no information on the use of guaifenesin in lactation

Fertility

No known effects

4.7 Effects on ability to drive and use machines

This product has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Adverse events which have been associated with guaifenesin are given below, tabulated by system organ class and frequency. Frequencies are defined as: Very common (≥1/10); Common (≥1/100 and <1/10); Uncommon (≥1/1000 and <1/100); Rare (≥1/10,000 and <1/1000); Very rare (<1/10,000); Not known (cannot be estimated from the available data). Within each frequency grouping, adverse events are presented in order of decreasing seriousness.

System Organ Class	Frequency	Adverse Events
Immune System Disorders	Not known	Hypersensitivity
Gastrointestinal Disorders	Not known	Abdominal discomfort, nausea, vomiting, diarrhoea

4.9 Overdose

Very large doses may cause nausea and vomiting.

Urinary calculi have also been reported in patients seeking to abuse the sympathomimetic component of a combination product which also resulted in taking large doses of guaifenesin of up to 24g per day. The development of kidney stones in a single active preparation of guaifenesin, like Mucinex, is extremely rare. The active substance is, however, rapidly metabolised and excreted in the urine. Patients should be kept under observation and treated symptomatically.

5. Pharmacological Properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Cough and cold preparations, Expectorants; **ATC Code:** R05CA03

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

5.2 Pharmacokinetic properties

Guaifenesin is readily absorbed from the gastrointestinal tract after oral administration and rapidly metabolised by oxidation to beta-(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 one hour.

5.3 Preclinical safety data

No preclinical findings of relevance to the prescriber have been reported.

6. Pharmaceutical Particulars

6.1 List of excipients

Each Mucinex and Maximum Strength Mucinex tablet also contains: microcrystalline cellulose, hypromellose, carbomer, sodium starch gylcollate, magnesium stearate and Brilliant Blue FCF (E133).

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25°C

6.5 Nature and content of container

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

Mucinex: packs of 10, 20, 40, 41, 60 and 100 tablets

Maximum Strength Mucinex: packs of 7, 14, 20, 21 and 28 tablets

Not all pack sizes are marketed.

6.6 Special precautions for disposal

Not applicable

7. Medicines Schedule

General Sale Medicine

Mucinex: Packs of 10, 20 and 40 tablets

Maximum Strength Mucinex: packs of 7, 14 and 21 tablets

Restricted Medicine

Mucinex: Packs of 41, 60 and 100 tablets

Maximum Strength Mucinex: packs of 21 and 28 tablets

8. Sponsor Details

Reckitt Benckiser (New Zealand) Limited

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Auckland, New Zealand

9. Date of First Approval

27 May 2010

10. Date of Revision of the Text

23 January 2019	Updated pregnancy warning with more up to date information
	Addition of diarrhoea to Adverse events
	Revise to SmPC format