

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Family Meltus Chesty Coughs Honey and Lemon Flavour Syrup

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of syrup contains 50 mg of Guaifenesin.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Syrup

A viscous orange syrup, clear to slightly opalescent.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Symptomatic relief of chesty cough and to soothe the throat.

4.2 Posology and method of administration

Dosage may be repeated 3 – 4 times daily.

Adults & children over 12 years:	Two to four 5ml spoonful.
Children 6 – 12 years:	Two 5ml spoonful.
Children 2 – 6 years:	One 5ml spoonful.
Children under 2 years:	On medical advice only.

4.3 Contraindications

Not applicable.

4.4 Special warnings and precautions for use

If symptoms persist or worsen, consult your doctor.

Keep out of reach of children.

Do not give to children under two years old, except under medical advice. Sunset yellow (E110) may cause allergic reactions.

Each 5ml dose contains up to 3.3g of sucrose, this should be taken into account if you have diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, consult your doctor before taking this product.

4.5 Interaction with other medicinal products and other forms of interaction

Not applicable.

4.6 Pregnancy and lactation

The product should not be used unless considered essential by the physician.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Gastro-intestinal discomfort has been reported.

4.9 Overdose

Very large doses may cause nausea and vomiting, it is however rapidly metabolised and excreted in the urine. The patient should be kept under observation and treated symptomatically.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Guaifenesin is an expectorant.

The sugar, honey & glycerin have a demulcent effect.

5.2 Pharmacokinetic properties

Guaifenesin is absorbed from the gastrointestinal tract. It is metabolised and excreted in the urine.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified honey
Sunset yellow (E110)
Sucrose, granular
Glycerol
Tolu flavour solution
Sodium Benzoate (E211)
Citric Acid Monohydrate
Lemon oil terpeneless
Isopropyl Alcohol
Sodium cyclamate
Purified water

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 contents of container

Amber glass drop bottle with tamper evident polypropylene copolymer cap with unfaced closed cell expanded polyethylene wad, packed in an outer carton, containing 150 ml of product.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Cupal Limited
SSL International
Tubiton House
Oldham
OL1 3HS
UK

8 MARKETING AUTHORISATION NUMBER

PA 258/38/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 9 January 1990

Date of last renewal: 9 January 2005

10 DATE OF REVISION OF THE TEXT

August 2005