SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Care Chesty Cough 200mg/15ml Syrup

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

INGREDIENT	QTY	UNIT	DOSE
Guaifenesin	200	mg	15 ml

Excipients with known effect

This medicine contains, per 15ml:

Sorbitol 3.07g

Propylene glycol 25.1mg

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Syrup.

Deep red coloured, thick, syrupy liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

To loosen stubborn mucus and clear chesty coughs.

4.2 Posology and method of administration

For oral use.

Adults, the Elderly and Children 12 years and over: 3 x 5ml spoonfuls

The dose should not be repeated more frequently than every 6 hours.

Not more than 3 doses should be taken in any 24 hours.

Do not take more medicine than the label tells you to.

This product is contraindicated in children under the age of 12 years (see section 4.3).

Do not take with any other cough and cold medicine.

4.3 Contraindications

Known hypersensitivity to any of the ingredients - Porphyria.

Not to be used in children under the age of 12 years.

4.4 Special warnings and precautions for use

Keep out of the sight and reach of children.

If symptoms persist consult your doctor.

Ingredients with specified warnings

This medicine contains less than 1mmol sodium (23mg) per dose, that is to say essentially 'sodium-free'.

This medicine contains 4.4g sorbitol in each 15ml dose. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

This medicine contains 25.1mg propylene glycol in each 15ml dose.

Contains Ponceau 4R E124 which may cause allergic reactions.

4.5 Interaction with other medicinal products and other forms of interaction

None reported.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no or limited amount of data from the use of Guaifenesin in pregnant women. As a result, this product is not recommended during pregnancy or in women of childbearing potential not using contraception.

Lactation

It is unknown whether Guaifenesin/metabolites are excreted in human milk therefore a risk to newborns/infants cannot be excluded. As a result, this product is not recommended during breast-feeding.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Adverse reactions are listed below by system organ class and frequency. Frequencies are defined as:

Very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1000 to <1/100), rare (≥1/10,000 to<1/1000) and very rare (<1/10,000), not known (cannot be estimated from the available data)

Immune system disorders
Unknown: hypersensitivity reactions

Gastrointestinal disorders
Unknown: Abdominal discomfort, nausea and vomiting

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for 'MHRA Yellow Card' in the Google Play or Apple App Store.

4.9 Overdose

Very large doses of Guaifenesin can cause nausea and vomiting. Vomiting should be treated by fluid replacement and monitoring of electrolytes.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Expectorants

ATC code: R05CA03

Mechanism of action/effect
Guaifenesin is a well-known expectorant. Such expectorants are known to increase the volume of secretions in the respiratory tract and therefore to facilitate their removal by ciliary action and coughing.

5.2 Pharmacokinetic properties

Absorption and Fate:
Guaifenesin is absorbed from the gastro-intestinal tract. It is metabolised and excreted in the urine.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber, which are additional to those already included in other sections of the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerin (E422)
Sorbitol 70% Solution Non-Crystallising (E420)
Sodium Cyclamate (E952)
Sodium Saccharin (E954)
Carrageenan
Anise, blackcurrant and menthol flavour (contains triacetin (E1518), propylene glycol (E1520)
Potassium Sorbate (E202)
Ponceau 4R (E124)
Caramel (E150)
Purified Water

6.2 Incompatibilities

None.

6.3 Shelf life

Three years.

6.4 Special precautions for storage

Do not store above 25ºC.

6.5 Nature and contents of container

150ml and 300ml amber glass bottles embossed “Care” with a 28mm, CRC, Tamper Evident, EPE/Alu/Melinex Lined Cap.

6.6 Special precautions for disposal

Shake well before use.

7 MARKETING AUTHORISATION HOLDER

Thornton & Ross Limited
Linthwaite
Huddersfield
HD7 5QH
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 00240/0592

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

20/12/2024

10 DATE OF REVISION OF THE TEXT

20/12/2024