



Medicines & Healthcare products  
Regulatory Agency

# **Public Assessment Report**

## **National Procedure**

**Care Chesty Cough 200mg/15ml Syrup**  
**Guaifenesin 200mg/15ml Syrup**

**guaifenesin**

**PL 00240/0592**

**PL 00240/0594**

**Thornton & Ross Limited**

## LAY SUMMARY

### Care Chesty Cough 200mg/15ml Syrup, Guaifenesin 200mg/15ml Syrup guaifenesin

This is a summary of the Public Assessment Report (PAR) for Care Chesty Cough 200mg/15ml Syrup, Guaifenesin 200mg/15ml Syrup. It explains how these products were assessed and their authorisation recommended, as well as their conditions of use. It is not intended to provide practical advice on how to use these products.

These products will be referred to as Guaifenesin in this lay summary for ease of reading.

For practical information about using Guaifenesin, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

#### **What is Guaifenesin and what is it used for?**

These applications are the same as Covonia Chesty Cough Sugar Free Syrup (PL 00240/0380) which are already authorised.

The Company responsible for Covonia Chesty Cough Sugar Free Syrup has agreed that its scientific data can be used as the basis for the grant of identical licences for Guaifenesin.

Guaifenesin is used to loosen stubborn mucus (phlegm) and provide relief from chesty coughs.

#### **How does Guaifenesin work?**

This medicine contains guaifenesin, which is an expectorant to help loosen phlegm.

#### **How is Guaifenesin used?**

The pharmaceutical form of these medicines is a syrup and the route of administration is oral (by mouth).

The patient should shake the bottle well before use.

**Adults, the elderly and children 12 years or older:** 3 x 5ml spoonfuls.

Each dose should be taken as required, but the patient should not repeat the dose more frequently than every 6 hours. Not more than 3 doses should be taken in any 24 hours.

The patient should not take more medicine than the leaflet tells them to.

Guaifenesin should not be given to children under 12 years of age.

Guaifenesin should not be taken with any other cough and cold medicine.

For further information on how Guaifenesin is used, refer to the PILs and Summaries of Product Characteristics (SmPCs) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

These medicines can be obtained without a prescription.

The patient should always take the medicine exactly as their doctor/pharmacist has told them. The patient should check with their doctor or pharmacist if they are not sure.

### **What benefits of Guaifenesin have been shown in studies?**

Guaifenesin is considered identical to the previously authorised product with the same benefits and risks. No new studies have been provided for Guaifenesin, however, reference is made to the studies for Covonia Chesty Cough Sugar Free Syrup.

### **What are the possible side effects of Guaifenesin?**

For the full list of all side effects reported with these medicines, see Section 4 of the PIL or the SmPCs available on the MHRA website.

If a patient gets any side effects, they should talk to their doctor, pharmacist or nurse. This includes any possible side effects not listed in the product information or the PIL that comes with the medicine. Patients can also report suspected side effects themselves, or a report can be made on their behalf by someone else who cares for them, directly via the Yellow Card scheme at <https://yellowcard.mhra.gov.uk> or search for 'MHRA Yellow Card' online. By reporting side effects, patients can help provide more information on the safety of this medicine.

Guaifenesin is considered to be identical to the previously authorised product with the same benefits and risks.

### **Why were Guaifenesin approved?**

The MHRA decided that the benefits of Guaifenesin are greater than the risks and recommended that these medicines are approved for use.

### **What measures are being taken to ensure the safe and effective use of Guaifenesin?**

As for all newly-authorised medicines, a Risk Management Plan (RMP) has been developed for Guaifenesin. The RMP details the important risks of Guaifenesin, how these risks can be minimised, any uncertainties about Guaifenesin (missing information), and how more information will be obtained about the important risks and uncertainties.

There are no safety concerns associated with use of Guaifenesin.

The information included in the SmPC and the PIL is compiled based on the available quality, non-clinical and clinical data, and includes appropriate precautions to be followed by healthcare professionals and patients. Side effects of Guaifenesin are continuously monitored and reviewed including all reports of suspected side-effects from patients, their carers, and healthcare professionals.

An RMP and a summary of the pharmacovigilance system have been provided with these applications and are satisfactory.

### **Other information about Guaifenesin**

Marketing Authorisations were granted in the UK on 20 December 2024.

The full PAR for Guaifenesin follows this summary.

This summary was last updated in February 2025.

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## **I. INTRODUCTION**

Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) considered that the applications for Care Chesty Cough 200mg/15ml Syrup, Guaifenesin 200mg/15ml Syrup (PL 00240/0592, PL 00240/0594) could be approved.

The products are approved for the following indication:

- To loosen stubborn mucus and clear chesty coughs.

The active substance, 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.

These are national abridged applications approved under Regulation 56 of The Human Medicines Regulation 2012, as amended (previously Article 10c of Directive 2001/83/EC, as amended) as informed consent applications. The applications cross-refer to the reference product Covonia Chesty Cough Sugar Free Syrup (PL 00240/0380).

No new non-clinical or clinical data have been supplied and none are required for these informed consent applications.

Suitable justification has been provided for non-submission of an Environmental Risk Assessment (ERA). As the applications are for identical versions of an already authorised product, no increase in environmental exposure is anticipated and no ERA is required.

The MHRA has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place for these products at all sites responsible for the manufacture, assembly and batch release of these products.

A Risk Management Plan (RMP) and a summary of the pharmacovigilance system have been provided with these applications and are satisfactory.

National marketing authorisations were granted in the UK on 20 December 2024.

## II. EXPERT REPORT

The applicant cross-refers to the data for Covonia Chesty Cough Sugar Free Syrup (Thornton & Ross Limited), to which these applications are claimed to be identical. This is acceptable.

## III. ASSESSOR'S COMMENTS ON THE PRODUCT INFORMATION

### Summaries of Product Characteristics (SmPCs)

The SmPCs are in line with that for Covonia Chesty Cough Sugar Free Syrup, dated 04/08/2021.

### PATIENT INFORMATION LEAFLET

Leaflet texts have been provided which has been aligned with that for Covonia Chesty Cough Sugar Free Syrup, dated for 08/2020.

### LABEL

Label texts have been provided.

## IV. QUALITY ASPECTS

### IV.1 Drug Substance

#### Drug substance specification

The source of the active substance is in line with the cross-reference product. The proposed drug substance specification is consistent with the details registered for the cross-reference product.

### IV.2. Drug Product

#### Name

The products have been named in line with current requirements.

#### Strength, pharmaceutical form, route of administration, container and pack sizes

Care Chesty Cough 200mg/15ml Syrup and Guaifenesin 200mg/15ml Syrup are to be available in amber glass bottles in 150ml and 300ml pack sizes.

The appearance of the products is identical to that of the cross-reference product.

The proposed shelf life of the product is 36 months with the recommended storage condition 'Do not store above 25°.

The proposed packaging, shelf life and storage conditions are consistent with the details registered for the reference product.

#### Legal status

General Sales List (GSL) medicine.

#### Manufacturers

The proposed manufacturing sites are consistent with the details registered for the cross-reference product and evidence of Good Manufacturing Practice (GMP) compliance has been provided.

#### Qualitative and quantitative compositions

The composition of the proposed products is consistent with the details registered for the cross-reference product.

### **Manufacturing process & control of critical steps**

The proposed manufacturing processes and process controls are consistent with the details registered for the reference product and the maximum batch size is stated.

### **Finished product release/shelf life specifications**

The finished product specifications at release and shelf-life are in line with the details registered for the cross-reference product.

### **TSE Compliance**

No excipients of animal or human origin are used in the final products.

These products do not contain or consist of genetically modified organisms (GMO).

## **V. NON-CLINICAL ASPECTS**

As these applications are submitted under Regulation 56 of The Human Medicines Regulation 2012, as amended, (as informed consent applications) no new non-clinical data have been supplied and none are required.

## **VI. CLINICAL ASPECTS**

As these applications are submitted under Regulation 56 of The Human Medicines Regulation 2012, as amended, (as informed consent applications) no new clinical data have been supplied and none are required.

## **VII. RISK MANAGEMENT PLAN (RMP)**

The applicant has submitted an RMP, in accordance with the requirements of Regulation 182 of The Human Medicines Regulation 2012, as amended. The applicant proposes only routine pharmacovigilance and routine risk minimisation measures for all safety concerns. This is acceptable.

## **VIII. USER CONSULTATION**

Text drafts of the Patient Information Leaflets (PILs) were presented. A commitment to provide mock-ups and evidence of user consultation of the PILs to the MHRA prior to marketing was accepted.

## **IX. OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION**

The quality of the products is acceptable, and no new non-clinical or clinical safety concerns have been identified. The applicant's products are identical to the cross-reference product. The benefit/risk balance is, therefore, considered to be the same as for the cross-reference product and positive.

The Summaries of Product Characteristics (SmPCs), Patient Information Leaflets (PILs) and labelling are satisfactory, in line with current guidelines and consistent with the cross-reference products.

In accordance with legal requirements, the current approved UK versions of the SmPCs and PILs for these products are available on the MHRA website.

## TABLE OF CONTENT OF THE PAR UPDATE

Steps taken after the initial procedure with an influence on the Public Assessment Report (non-safety variations of clinical significance).

Please note that only non-safety variations of clinical significance are recorded below and in the annexes to this PAR. The assessment of safety variations where significant changes are made are recorded on the MHRA website or European Medicines Agency (EMA) website. Minor changes to the marketing authorisation are recorded in the current SmPC and/or PIL available on the MHRA website.

<b>Application type</b>	<b>Scope</b>	<b>Product information affected</b>	<b>Date of grant</b>	<b>Outcome</b>	<b>Assessment report attached Y/N</b>