



Medicines & Healthcare products
Regulatory Agency

Public Assessment Report

National Procedure

Covonia Chesty Cough Anise & Blackcurrant Flavour Sugar Free Syrup

Guaifenesin

PL 00240/0627

Thornton & Ross Limited

LAY SUMMARY

Covonia Chesty Cough Anise & Blackcurrant Flavour Sugar Free Syrup Guaifenesin

This is a summary of the Public Assessment Report (PAR) for Covonia Chesty Cough Anise & Blackcurrant Flavour Sugar Free Syrup. It explains how this product was assessed and its authorisation recommended, as well as its conditions of use. It is not intended to provide practical advice on how to use this product.

This product will be referred to as Covonia Chesty Cough Anise & Blackcurrant Flavour Sugar Free Syrup in this lay summary for ease of reading.

For practical information about using Covonia Chesty Cough Anise & Blackcurrant Flavour Sugar Free Syrup, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

What is Covonia Chesty Cough Anise & Blackcurrant Flavour Sugar Free Syrup and what is it used for?

This application is the same as Covonia Chesty Cough Sugar Free Syrup (PL 00240/0380) which is already authorised.

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

How does Covonia Chesty Cough Anise & Blackcurrant Flavour Sugar Free Syrup work?

Covonia Chesty Cough Anise & Blackcurrant Flavour Sugar Free Syrup contains guaifenesin which is an expectorant to help loosen phlegm.

How is Covonia Chesty Cough Anise & Blackcurrant Flavour Sugar Free Syrup used?

The pharmaceutical form of this medicine is a syrup and the route of administration is taken by mouth (oral use).

Shake the bottle well before use.

Dose

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.

This medicine must *not* be given to children under 12 years.

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

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

If the patient's symptoms persist or worsen, the patient should contact their doctor or pharmacist.

Patients that:

- are allergic to guaifenesin or any of the other ingredients should not take this medicine.
- suffer from porphyria, which is a blood disorder that causes skin or nervous system problems.

For further information on how Covonia Chesty Cough Anise & Blackcurrant Flavour Sugar Free Syrup is used, refer to the PIL and Summary of Product Characteristics (SmPC) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

This medicine 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 Covonia Chesty Cough Anise & Blackcurrant Flavour Sugar Free Syrup have been shown in studies?

Covonia Chesty Cough Anise & Blackcurrant Flavour Sugar Free Syrup is considered identical to the previously authorised product/products with the same benefits and risks. [No new studies have been provided for Covonia Chesty Cough Anise & Blackcurrant Flavour Sugar Free Syrup, however, reference is made to the studies for Covonia Chesty Cough Sugar Free Syrup.

What are the possible side effects of Covonia Chesty Cough Anise & Blackcurrant Flavour Sugar Free Syrup?

For the full list of all side effects reported with this medicine, see Section 4 of the PIL or the SmPC 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.

Covonia Chesty Cough Anise & Blackcurrant Flavour Sugar Free Syrup is considered to be identical to the previously authorised product/products with the same benefits and risks.

Why was Covonia Chesty Cough Anise & Blackcurrant Flavour Sugar Free Syrup approved?

The MHRA decided that the benefits of Covonia Chesty Cough Anise & Blackcurrant Flavour Sugar Free Syrup are greater than the risks and recommended that this medicine is approved for use.

What measures are being taken to ensure the safe and effective use of Covonia Chesty Cough Anise & Blackcurrant Flavour Sugar Free Syrup?

As for all newly-authorised medicines, a Risk Management Plan (RMP) has been developed for Covonia Chesty Cough Anise & Blackcurrant Flavour Sugar Free Syrup. The RMP details the important risks of Covonia Chesty Cough Anise & Blackcurrant Flavour Sugar Free Syrup, how these risks can be minimised, any uncertainties about Covonia Chesty Cough Anise &

Blackcurrant Flavour Sugar Free Syrup (missing information), and how more information will be obtained about the important risks and uncertainties.

There are no safety concerns associated with use of Covonia Chesty Cough Anise & Blackcurrant Flavour Sugar Free Syrup.

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 Covonia Chesty Cough Anise & Blackcurrant Flavour Sugar Free Syrup 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 this application and are satisfactory.

Other information about Covonia Chesty Cough Anise & Blackcurrant Flavour Sugar Free Syrup

A marketing authorisation was granted in the UK on 25 September 2025.

The full PAR for Covonia Chesty Cough Anise & Blackcurrant Flavour Sugar Free Syrup follows this summary.

This summary was last updated in November 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 application for Covonia Chesty Cough Sugar Free Syrup (PL 00240/0627) could be approved.

The product is approved for the following indication:

To loosen stubborn mucus and clear chesty coughs.

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.

This is a national abridged application approved under Regulation 56 of The Human Medicines Regulation 2012, as amended (previously Article 10c of Directive 2001/83/EC, as amended) as an informed consent application. The application cross-refers 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 this informed consent application.

Suitable justification has been provided for non-submission of an Environmental Risk Assessment (ERA). As the application is for an identical version 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 this product at all sites responsible for the manufacture, assembly and batch release of this product.

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

A national marketing authorisation was granted in the UK on 25 September 2025.

II. EXPERT REPORT

The applicant cross-refers to the data for Covonia Chesty Cough Sugar Free Syrup (PL 00240/0380) to which this application is claimed to be identical. This is acceptable.

III. ASSESSOR'S COMMENTS ON THE PRODUCT INFORMATION SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

The SmPC is in line with that for Covonia Chesty Cough Sugar Free Syrup (PL 00240/0380), dated 08/2021.

PATIENT INFORMATION LEAFLET

PIL QRD text has been provided, the content of which has been aligned with that for Covonia Chesty Cough Sugar Free Syrup (PL 00240/0380), dated 08/2020.

A label-leaflet, dated 10/2024, is currently registered for the cross-reference product.

LABEL

Label text has been provided.

IV. QUALITY ASPECTS

IV.1 Drug Substance

Drug substance specification(s)

The source(s) of the active substance(s) 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 product has been named in line with current requirements.

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

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

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

The proposed shelf life of the product is three years with with the recommended storage condition “Do not store above 25°C”.

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 site(s) 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 product 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.

This product does not contain or consist of genetically modified organisms (GMO).

V. NON-CLINICAL ASPECTS

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

VI. CLINICAL ASPECTS

As this application is submitted under Regulation 56 of The Human Medicines Regulation 2012, as amended, (as an informed consent application) 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

A text draft of the Patient Information Leaflet (PIL) was presented. A commitment to provide a mock-up and evidence of user consultation of the PIL to the MHRA prior to marketing was accepted.

IX. OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION

The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. The applicant's product is 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 Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and labelling are satisfactory, in line with current guidelines and consistent with the cross-reference product.

In accordance with legal requirements, the current approved UK versions of the SmPC and PIL for this product are available on the MHRA website.

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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.

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