

**IPAR**



**Public Assessment Report for a  
Traditional Herbal Medicinal Product  
for Human Use**

---

Benylin Herbal Chesty Coughs Syrup  
Ivy leaf dry extract

TR23490/001/001  
TR Holder JNTL Consumer Health I (Ireland) Limited

**CONTENTS**

I. INTRODUCTION

II. QUALITY ASPECTS

III. NON-CLINICAL ASPECTS

IV. CLINICAL ASPECTS

V. OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

VI. REVISION DATE

VII. UPDATE

## I. INTRODUCTION

Specific provisions were introduced for traditional herbal medicinal products (THMPs) in accordance with the Traditional Herbal Medicinal Products Directive (2004/24/EC). The national regulations, the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007) which implement this Directive came into force on 23rd July 2007. Consequently, the Health Products Regulatory Authority (HPRA) has established the Traditional Herbal Medicinal Products Registration Scheme.

The Public Assessment Report reflects the scientific conclusion reached by the HPRA at the end of the evaluation process and provides a summary of the grounds for approval of a Certificate of Traditional Use Registration for a specific traditional herbal medicinal product for human use. It is made available by the HPRA for information to the public, after deletion of commercially sensitive information. The legal basis for its creation and availability is contained in Article 21 of EC Directive 2001/83/EC, as amended by Directive 2004/27/EC and Directive 2004/24/EC. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the traditional herbal medicinal product for marketing in Ireland.

Based on the review of the data on quality, safety and traditional use, the HPRA has granted JNTL Consumer Health I (Ireland) Limited a Certificate of Traditional Use Registration for Benylin Herbal Chesty Coughs Syrup, containing a dry extract of ivy leaf.

This application is for a traditional herbal medicinal product as defined by Article 16a(1) of Directive 2001/83/EC as amended and was submitted as part of the Traditional Herbal Medicinal Product Registration Scheme.

The Summary of Product Characteristics (SmPC) for this traditional herbal medicinal product is available on the HPRA's website.

<b>Name of the product</b>	Benylin Herbal Chesty Coughs Syrup
<b>Name(s) of the active substance(s) (INN)</b>	Ivy leaf dry extract
<b>Pharmacotherapeutic classification (ATC Code)</b>	R05CA12
<b>Pharmaceutical form and strength(s)</b>	Syrup
<b>TR Number(s) in Ireland</b>	TR23490/001/001
<b>TR Holder</b>	JNTL Consumer Health I (Ireland) Limited

## II. QUALITY ASPECTS

This application is for Benylin Herbal Chesty Coughs Syrup. The active ingredient of Benylin Herbal Chesty Coughs Syrup is obtained from ivy leaf.

### II.1 S.1 Herbal Substance

The herbal substance is Ivy leaf, described in the European Pharmacopoeia, and is produced in accordance with the principles of good agricultural and collection practice (GACP).

The herbal substance specification is considered adequate to control the quality and meets current pharmacopoeial requirements. Batch analytical data demonstrating compliance with this specification have been provided.

### II.2 S.2 Herbal preparation

The herbal preparation is a dry extract of ivy leaf, and is manufactured in accordance with the principles of good manufacturing practice (GMP).

The herbal preparation specification is considered adequate to control the quality and meets current pharmacopoeial requirements. Batch analytical data demonstrating compliance with this specification have been provided.

### II.3 Medicinal product

#### P.1 Composition

The composition of the medicinal product is stated in sections 2 and 6.1 of the SmPC. A description of the product is included in section 3 of the SmPC.

## P.2 Pharmaceutical Development

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

## P.3 Manufacture of the Product

The product is manufactured in accordance with the principles of GMP at suitably qualified manufacturing sites.

The manufacturing process has been validated according to relevant European/ICH guidelines and the process is considered to be sufficiently validated.

## P.4 Control of Other Substances (Excipients/*Ancillary Substances*)

All ingredients comply with Ph. Eur.

## P.5 Control of the Finished Product

The Finished Product Specification is based on the pharmacopoeial monograph for liquid preparations for oral use and the tests and control limits are considered appropriate for this type of product.

The analytical methods used are described in sufficient detail and are supported by validation data.

Batch analytical data for a number of batches from the proposed production site(s) have been provided and demonstrate the ability of the manufacturer to produce batches of finished product of consistent quality.

## P.6 Packaging material

The approved packaging for this product is described in section 6.5 of the SmPC.

Evidence has been provided that the packaging materials comply with Ph. Eur. and/or EU legislation on materials intended for use with foodstuffs.

## P.7 Stability of the Finished Product

Stability data on the finished product in the proposed packaging have been provided in accordance with EU guidelines and support the shelf-life and storage conditions listed in sections 6.3 and 6.4 of the SmPC.

## II.4 Conclusion on quality

The important quality characteristics of the product are well-defined and controlled. Satisfactory pharmaceutical documentation has been provided, assuring consistent quality of Benylin Herbal Chesty Coughs Syrup.

## III. NON-CLINICAL ASPECTS

Benylin Herbal Chesty Coughs Syrup is a traditional herbal medicinal product as defined by Article 16a (1) of Directive 2001/83/EC as amended.

No new non-clinical studies have been submitted. Given the type of application and limited data available, it is not possible to assess if the safety package for the phytochemical constituents of Benylin Herbal Chesty Coughs Syrup is acceptable to the standards of today's GLP and safety testing requirements.

An expert report on safety has been provided which includes an appropriate review of the available literature. Overall, the information presented demonstrating traditional use is considered to be acceptable and the lack of provision of a complete standard safety package is in line with the EMA 'Guideline on Non-clinical Documentation for Herbal Medicinal Products in Applications for Marketing Authorisation (bibliographical and mixed applications) and in Applications for Simplified Registration' (EMEA/HMPC/32116/05).

A GLP compliant Ames test has been submitted which did not reveal a risk of genotoxicity associated with Benylin Herbal Chesty Coughs Syrup. Carcinogenicity and reproductive toxicity testing have not been conducted.

An environmental risk assessment is not required for herbal medicinal products according to guidance CPMP/SWP/4447/00.

#### **IV. CLINICAL ASPECTS**

This is a national application submitted by JNTL Consumer Health I (Ireland) Limited under Article 16c of Directive 2001/83/EC, as amended.

Benylin Herbal Chesty Coughs Syrup is a traditional herbal medicinal product used as an expectorant for the relief of chesty coughs associated with the common cold, exclusively based on long-standing use.

##### **IV.1 Clinical Efficacy**

There is no requirement under the Traditional Herbal Registration Scheme to prove scientifically that the product is efficacious, the registration is based exclusively upon the longstanding use of Benylin Herbal Chesty Coughs Syrup as a traditional herbal medicine and not upon data generated from clinical trials.

Article 16c1(c) of Directive 2001/83/EC requires the applicant to provide bibliographic or expert evidence to show that the medicinal product in question, or a corresponding product, has been in medicinal use throughout a period of at least 30 years, including at least 15 years within the Community. With regard to this traditional use data, the requirements of Article 16c1(c) have been met.

The efficacy of this traditional herbal medicinal product is plausible on the basis of long standing use and experience.

The indication proposed for Benylin Herbal Chesty Coughs Syrup is in line with traditional indications recorded and hence, compatible with the requirements of the Traditional Herbal Medicinal Products Directive 2004/24/EC.

##### **IV.2 Clinical Safety**

In accordance with Article 16c1(d) the applicant has provided a bibliographic review of the safety data together with an expert report.

The maximum dosage is 4ml of syrup up to 3 times per day; it is recommended that this dosage is not exceeded.

The use of Benylin Herbal Chesty Coughs Syrup should be avoided in those who are allergic to ivy leaf and in those allergic to any of the other ingredients of this product.

Benylin Herbal Chesty Coughs Syrup is intended for oral short-term use only. It is recommended that if symptoms persist, worsen or do not improve after 7 days use of the product, a doctor or pharmacist should be consulted.

Benylin Herbal Chesty Coughs Syrup is not recommended for use in children under 12 years as safety data is lacking and medical advice should be sought.

As safety during pregnancy and breast-feeding has not been established, use during pregnancy and breast-feeding is not recommended.

Each 4 ml of syrup contains 2832 mg of sorbitol (E 420). Patients with hereditary fructose intolerance (HFI) should not take/be given this medicinal product. Sorbitol may cause gastrointestinal discomfort and mild laxative effect. The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account. The content of sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use administered concomitantly.

The possible side effects that may occur after ingesting Benylin Herbal Chesty Coughs Syrup include nausea, vomiting, diarrhoea, urticaria (hives), skin rash and shortness of breath. Patients are advised to contact their doctor or pharmacist if side effects become troublesome or other side effects occur.

In conclusion, this product proves not to be harmful in the specified conditions of use based on the review of safety data, expert report and additional data provided.

#### IV.3 Pharmacovigilance

It should be noted that in accordance with Article 16g of Directive 2001/83/EC, as amended, the pharmacovigilance requirements described in Articles 101- 108 of Directive 2001/83/EC, as amended, also apply in respect of traditional herbal medicinal products.

#### V. OVERALL CONCLUSIONS

The important quality characteristics of the product are well-defined and controlled. Satisfactory pharmaceutical documentation has been provided, assuring consistent quality of Benylin Herbal Chesty Coughs Syrup.

The HPRA, on the basis of the data submitted, considered that Benylin Herbal Chesty Coughs Syrup demonstrated adequate evidence of traditional use for the approved indication(s) and no new non-clinical or clinical safety concerns have been identified.

A Certificate of Traditional Use Registration for Benylin Herbal Chesty Coughs Syrup is granted.

#### DATE OF APPROVAL

X

#### VI. REVISION DATE

#### VII. UPDATES

SCOPE	PROCEDURE NUMBER	PRODUCT INFORMATION AFFECTED	DATE OF START OF PROCEDURE	DATE OF END OF PROCEDURE
New Herbal	CRN00CYRH	SmPC Sections 1 to 9, Product Information Leaflet, Public Assessment Report	15 <sup>th</sup> November 2024	14 <sup>th</sup> November 2029