

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Benylin Dry & Tickly Coughs Syrup

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient	per 5 ml
Glycerol	0.75 ml
Sucrose	1.71g

Excipients with known effect:

Liquid Glucose	2.342g
Propylene glycol (E1520)	24mg
Sodium benzoate (E211)	10mg
Ethanol	5mg
Sodium	1.62mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Syrup

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

For the relief of irritating, tickling dry coughs and sore throats.

4.2 Posology and method of administration

Posology:

Adults and children over 5 years: 10 ml

Children 1 – 5 years: 5 ml

The dose may be repeated three or four times a day.

Children under one year: Not to be given to children under 1 year.

Elderly:

There is no need for dosage reduction in the elderly.

Method of administration:

For oral use.

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1.

Do not give to children under one year.

4.4 Special warnings and precautions for use

Diabetics should take note that sucrose and glycerol may affect blood sugar levels.

Information relating specifically to excipients in the formulation.

This medicine contains sucrose and glucose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

This medicine contains 24 mg propylene glycol in each 5 ml which is equivalent to 4.8mg/ml.

This medicine contains 10 mg sodium benzoate (E211) in each 5ml.

This medicine contains 5 mg of alcohol (ethanol) in each 5 ml dose. The amount in 5 ml of this medicine is equivalent to less than 1 ml beer or wine. The small amount of alcohol in this medicine will not have any noticeable effects.

This medicine contains less than 1 mmol sodium (23 mg) per 5 ml, that is to say essentially 'sodium-free'.

If symptoms persist for more than 3 days or get worse, patients should stop use and consult a doctor.

4.5 Interactions with other medicinal products and other forms of Interaction

No clinically significant interactions known.

4.6 Fertility, pregnancy and lactation

The safety of this product during pregnancy and lactation has not been established, but is not considered to constitute a hazard during these periods.

4.7. *Effects on ability to drive and use machines*

This medicine has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

No known adverse effects.

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

Management:

Overdosage would not be expected to cause any problems and treatment would be merely symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Cough suppressants and mucolytics, ATC code: R05FB01

Glycerol and sucrose have demulcent properties and will soothe irritated sore throats and possibly block sensory cough receptors within the respiratory tract.

5.2 Pharmacokinetic properties

Absorption

Glycerol is readily absorbed from the gastrointestinal tract.

Sucrose is hydrolysed in the small intestine by the enzyme sucrase to glucose and fructose which are then absorbed.

Distribution

Glycerol combines with free fatty acids in the liver to form triglycerides which are distributed to adipose tissues.

There are limited data on the distribution of oral sucrose in man.

Metabolism

Glycerol undergoes extensive metabolism principally in the liver and to a lesser extent in the kidneys. Glycerol is metabolised to glucose or glycogen or oxidised to carbon dioxide and water. The hydrolysis products of sucrose are metabolized through different pathways in the body. Glucose elicits a glycaemic and insulinaemic response that stimulates its uptake into cells while fructose is mainly metabolized in the liver via an insulin-independent pathway not regulated by energy supply. Fructose may be converted into trioses that can be used for the de novo synthesis of triglycerides and cholesterol.

Elimination

It may also be excreted in the urine unchanged.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on studies of repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid monohydrate
Sodium benzoate (E211)
Cough syrup 513277 flavour (containing anise oil, liquorice, propylene glycol (E1520), ethanol (alcohol))
Black treacle
Liquid glucose
Purified water

6.2. Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

A white flint glass bottle with an aluminium roll-on pilfer proof cap with a flowed in liner, or a triseal (LDPE/EPE/LDPE) liner.

Alternative cap: A wadless polypropylene tamper evident cap.

Pack size: 200 ml

Or

An amber glass bottle with an aluminium roll-on pilfer proof cap with a triseal (LDPE/EPE/LDPE) liner.

Pack size: 125ml or 150ml

Or

An amber PET bottle with a child resistant polypropylene cap fitted with an expanded polyethylene liner.

Alternative cap: An aluminium roll-on pilfer proof cap with a flowed in liner, or a triseal (LDPE/EPE/LDPE) liner.

Pack size: 150ml or 300ml

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements for disposal.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

McNeil Products Limited
50 – 100 Holmers Farm Way
High Wycombe
Buckinghamshire

HP12 4EG
UK

8. MARKETING AUTHORISATION NUMBER(S)

PL 15513/0142

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

11th January 2005

10 DATE OF REVISION OF THE TEXT

10/03/2021