SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Benylin Dry & Tickly Cough Blackcurrant Syrup
Benylin Children's Dry Cough & Sore Throat Syrup
CalCough Children's Syrup

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient	Quantity per 5ml
Glycerol	0.75ml
Sucrose	1.7g

Excipient with known effect:

Liquid Glucose	2.15g
Propylene glycol	3.53mg
Sodium benzoate (E211)	10mg
Sodium	1.6mg
Benzyl alcohol	0.000053mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Syrup
A dark red, blackcurrant flavoured 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, elderly and children over 5 years: 10ml

Children 1 - 5 years: 5ml
The dose may be repeated three or four times a day.

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

Method of Administration
For oral administration.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

Do not give to children under one year.

4.4 Special warnings and special precautions for use

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

Patients with rare hereditary problems of fructose intolerance, glucose galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. If symptoms persist for more than 3 days or get worse, patients should stop use and consult a doctor.

This medicine contains 3.53mg propylene glycol (E1520) in each 5ml dose, which is equivalent to 0.71mg/ml.

This medicine contains 10mg sodium benzoate (E211) in each 5ml which is equivalent to 2mg/ml.

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

This medicine contains 0.000053mg benzyl alcohol in each 5ml which is equivalent to 0.000011mg/ml. Benzyl alcohol may cause allergic reactions. Ask your doctor or pharmacist for advice if you are pregnant or breast‑feeding or if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis"). Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist. This is due to an increased risk due to accumulation in young children.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically significant interactions known.

4.6 Fertility, pregnancy and lactation

The safety of this medicine 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 product has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Immune system disorder: hypersensitivity reactions, including anaphylaxis.

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:
Treatment should be 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 metabolised through different pathways in the body. Glucose elicits a glycaemic and insulinaemic response that stimulates its uptake into cells while fructose is mainly metabolised 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
Anthocyanin
Blackcurrant Flavour 1740.7107 IFF (containing benzyl alcohol and propylene glycol (E1520))
Blackcurrant Juice 1740.1436 IFF (containing benzyl alcohol and propylene glycol (E1520))
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

125ml, 150ml or 200ml white flint glass, or amber glass bottle with an aluminium roll-on pilfer-proof cap with a flowed in liner, or a triseal (LDPE/EPE/LDPE) liner.

Alternative caps: A wadless polypropylene tamper evident cap, or a child resistant polypropylene cap with a EPE liner.

A double ended measuring spoon of 1.25ml, 2.5ml and 5.0ml capacity may optionally be provided with the product.

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

PL 15513/0392

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

24 November 2014

10 DATE OF REVISION OF THE TEXT

19 July 2022