

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Glycerin and Blackcurrant Linctus

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Active Ingredient</u>	<u>Quantity per 5 ml</u>
Glycerin	0.75 ml
Liquid sugar	1.93 ml
(Equivalent to sucrose	1.7 g)
Excipients of known effect	
Glucose	0.8 g
Sodium Benzoate	10 mg

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral Solution (Linctus)

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

Adults, elderly 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.

For oral administration.

4.3 Contraindications

Hypersensitivity or intolerance to any of the ingredients.

4.4 Special warnings and special precautions for use

Contains 3.4 g of sucrose per 10ml dose. This should be taken into account in patients with Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Contains 1.6g of glucose per 10ml dose. This should be taken into account in patients with This medicine may be harmful to the teeth.

This medicine contains 20mg sodium benzoate in each 10 ml dose. Increase in bilirubinaemia following its displacement from albumin may increase neonatal jaundice which may develop into kernicterus (non-conjugated bilirubin deposits in the brain tissue).

This medicine contains less than 1 mmol sodium (23 mg) per 10ml dose, that is to say essentially 'sodium-free'.

Do not give to children under one year.

Keep all medicines out of the sight and reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically significant interactions known

4.6 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

None stated.

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

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Glycerin 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

Glycerin is readily absorbed from the gastrointestinal tract and undergoes extensive metabolism principally in the liver. It may be used in the synthesis of lipids, and is metabolised to glucose or glycogen or oxidised to carbon dioxide and water. It may also be excreted in the urine unchanged.

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

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid monohydrate
Sodium benzoate
Anthocyanin
Blackcurrant Flavour
Blackcurrant Juice
Liquid Glucose
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store below 25°C.

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 2.5ml and 5.0ml capacity may optionally be provided with the product.

6.6 Special precautions for disposal

None stated.

7 MARKETING AUTHORISATION HOLDER

The Boots Company PLC
1 Thane Road West
Nottingham NG2 3AA

Trading as: BCM

8 MARKETING AUTHORISATION NUMBER(S)

PL 00014/0307

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

14/03/1984 / 23/09/2005

10 DATE OF REVISION OF THE TEXT

26/07/2023