SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Vicks Cough Syrup with Honey for Dry and Irritating Coughs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredients

	% w/v	Specification
Levomenthol	0.125	EP

3. PHARMACEUTICAL FORM

Syrup for oral administration.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For symptomatic relief of dry, irritating cough associated with the common cold.

4.2 Posology and Method of Administration

Adults and children over 12 years:	10ml every 3 - 4 hours Maximum of 6 doses per day
Children 6-12 years:	5ml every 3 - 4 hours Maximum of 6 doses per day
Children under 6 years:	Not recommended

4.3 Contra-indications

Patients hypersensitive to menthol and propylene glycol.

4.4 Special warnings and precautions for use

If symptoms persist for more than 7 days, consult your doctor.

Each 10 ml adult dose contains 9g of **sugar** (sucrose and glucose). This should be taken into consideration by patients with diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, consult your doctor before taking this medicinal product.

This medicine contains 2 g **propylene glycol** in each 10 ml dose, and 1 g propylene glycol in each 5 ml dose.

If you suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

If you are pregnant or breast feeding, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

Diabetics should consult their doctor before using this product.

Not to be given to children under 6 years of age unless directed by a doctor.

If you are pregnant, consult your doctor before use.

Keep out of the reach of children.

4.5 Interactions with other Medicinal Products and other Forms of Interaction

None expected

4.6 Pregnancy and lactation

No specific information is available; however, the long history of use of menthol gives no evidence to suggest any adverse effects. As with all medicines in pregnancy or lactation, care should be taken and as precaution this product should not be used without medical advice during pregnancy or lactation.

4.7 Effects on Ability to Drive and Use Machines

None

4.8 Undesirable effects

None

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.

4.9 Overdose

Symptoms

Ingestion of excessive quantities of menthol is reported to cause symptoms similar to those seen after ingestion of camphor, including severe abdominal pain, nausea, vomiting, vertigo, ataxia, drowsiness, and coma.

Treatment of overdose

Treatment of menthol overdose should be based on symptoms presented.

5.1 Pharmacodynamic Properties

Menthol provides an antitussive action and the syrup base contributes a demulcent effect.

5.2 Pharmacokinetic Properties

It is hypothesised that menthol may have a topical effect. However, once swallowed, menthol is absorbed and metabolised to glucuronides which are mainly excreted in the urine.

5.3 Preclinical Safety Data

N/A

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Sucrose
Liquid Glucose
Honey
Propylene Glycol
Purified Water

6.2 Incompatibilities

None

6.3 Shelf Life

24 months

6.4 Special Precautions for Storage

Do not store above 25°C. Do not refrigerate.

6.5 Nature and contents of container

100ml, 120ml, 125ml, 150ml Or 200ml Brown Type III Coated Amber Glass Bottles with two piece crab claw seal (polypropylene) child resistant closure. Composed of two parts; an outer and inner part. The outer part does not come into contact with the product, whereas the inner part is in contact with the product. Not all pack sizes may be marketed.

6.6 Instruction for Use, Handling and Disposal

None

7 MARKETING AUTHORISATION HOLDER

Procter & Gamble (Health & Beauty Care) Ltd.
The Heights
Brooklands
Weybridge
Surrey
KT13 OXP

8. MARKETING AUTHORISATION NUMBER

PL 00129/0110

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

24th August 1992

10 DATE OF REVISION OF THE TEXT

06/10/2020