SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Buttercup Original Cough Syrup

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml of syrup contains:

3.1 microlitres of extract (as liquid extract) from Squill bulb (*Drimia maritima* (L.) Stearn.) (1:1)

Extraction solvent: Ethanol 65% v/v

2.5 microlitres of tincture from Capsicum Oleoresin (*Capsicum annuum* L. var. minimum (Miller) Heiser) (1:10)

Extraction solvent: Ethanol 96% v/v

5 ml of syrup also contains 99mg of ethanol, 1.8g sucrose, 1.3g fructose and 1.3g glucose (as Partial Invert Syrup), 3.5mg of sodium methyl hydroxybenzoate (E219), 1.5 mg of sodium propyl hydroxybenzoate (E217) carmoisine E122 and Sunset Yellow E110. (See Section 4.4 ‘Special warnings and precautions for use.’)

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Syrup

Reddish-brown oral liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A traditional herbal medicinal product used for the relief of coughs, colds and sore throats, based on traditional use only.

4.2 Posology and method of administration

For oral use only

Adults, the elderly and children over 12 years: Two 5 ml spoonfuls three times a day and at bedtime, if the cough is troublesome.

This product is not recommended for use in children under 12 years of age (See Section 4.4 special warnings and precautions for use.')

Duration of use:

Do not use for more than one week.

If symptoms worsen or persist after one week, consult a doctor or qualified healthcare practitioner.

4.3 Contraindications

Hypersensitivity to any of the active ingredients, or menthol or any of the excipients.

4.4 Special warnings and precautions for use

Do not exceed the stated dose.

If symptoms worsen or persist after one week, consult a doctor or qualified healthcare practitioner.

If dyspnoea, fever or purulent sputum occurs, a doctor or qualified healthcare practitioner should be consulted.

This product is not recommended for use in children under 12 years of age because data are not sufficient and medical advice should be sought.

This medicine contains 3.6 g sucrose, 2.6 g glucose and 2.6 g fructose (as Partial Invert Syrup) in each dose (10 ml). This should be taken into account in patients with diabetes mellitus.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. It may also be harmful to the teeth.

The additive effect of concomitantly administered products containing fructose (or sorbitol) and dietary intake of fructose (or sorbitol) should be taken into account. Patients with hereditary fructose intolerance should not be given this product.

This medicinal product contains 4.6% v/v ethanol (alcohol), i.e. up to 198 mg per 10ml dose, equivalent to 5ml beer, 2ml wine per dose.

The small amount of alcohol in this medicine will not have any noticeable effects.

Harmful for those suffering from alcoholism. To be taken into account in pregnant or breast feeding women, children and high risk groups such as patients with liver disease or epilepsy.

Contains Sunset yellow (E110) and Carmoisine (E122), which may cause allergic reactions.

Contains Sodium methyl hydroxybenzoate (E219) and Sodium propyl hydroxybenzoate (E217). May cause allergic reactions (possibly delayed).

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

4.5 Interaction with other medicinal products and other forms of interaction

No interactions studies have been performed.

Contains alcohol and should be avoided in patients taking other medicines known to interact with alcohol (e.g. metronidazole)

4.6 Fertility, Pregnancy and lactation

Safety during pregnancy and lactation has not been established. Due to the lack of data, use during pregnancy and lactation is not recommended.

Studies on the effects on fertility have not been performed.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive or operate machines have been performed.

Contains alcohol. See Section 2.

4.8 Undesirable effects

None reported.

If other adverse reactions occur, a doctor or a qualified healthcare practitioner should be consulted.

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

No cases reported.

Very high doses of Squill would be emetic and could be cardioactive.

Overdose of this product may result in alcohol intoxication and should be treated accordingly. The amount of alcohol in a full bottle is:

1.4 g in 75 ml, equivalent 34.1 ml beer or 14.2 ml wine

2.7 g in 150 ml, equivalent 68.3 ml beer or 28.4 ml wine

3.6 g in 200 ml, equivalent 91 ml beer or 37.9 ml wine

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended

5.2 Pharmacokinetic properties

Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended

5.3 Preclinical safety data

Tests on reproductive toxicity, carcinogenicity and genotoxicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Acacia Powder
Caramel Colour (E150)
Ethanol
Levomenthol
Clove Oil
Peppermint Oil
Sodium methyl hydroxybenzoate (E219)
Sodium propyl hydroxybenzoate (E217)
Potassium sorbate
Aniseed Flavour
Purified Water
Carmoisine (E122)
Sunset Yellow (E110)
Strong Ginger Tincture (ginger, ethanol, water)
Acetic Acid
Saccharin Sodium
Partial Invert Syrup (sucrose, fructose and glucose)

6.2 Incompatibilities

None known.

6.3 Shelf life

3 years (unopened).
28 days (after first opening the bottle)

6.4 Special precautions for storage

Do not store above 25˚C. Store in the original container

6.5 Nature and contents of container

Clear glass bottle with aluminium tamper-evident screw-cap: 75 ml, 150 ml, 200 ml, 300 ml

Amber glass bottle with aluminium tamper-evident screw-cap: 300 ml

Not all pack sizes may be marketed

6.6 Special precautions for disposal

There are no special precautions for disposal.

7 MARKETING AUTHORISATION HOLDER

Phoenix Labs Unlimited Company
Suite 12
Bunkilla Plaza
Bracetown Business Park
Clonee
County Meath
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

THR 35104/0055

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

29/04/2013

10 DATE OF REVISION OF THE TEXT

21/10/2024