Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Buttercup Bronchostop Cough Syrup

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

15 ml of syrup (~16.7 g) contains:

0.12 g of dry extract from Thymus vulgaris (L.) and Thymus zygis (L.) herba (thyme herb) (7-13:1) Extraction solvent: water and
3.35 g of marshmallow root syrup containing 0.83 g liquid extract from Althaea officinalis (L.) (marshmallow root) (DER 1: 12-14) Extraction solvent: water.

Excipients with known effect:
15 ml of syrup contains 12.53 mg of methyl parahydroxybenzoate (E218), 6.68 mg of propyl parahydroxybenzoate (E216), 4609.2 mg of xylitol (E967) and approximately 130 mg of total sugars from raspberry juice concentrate (containing sucrose, glucose and fructose).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral Syrup
Brown-red viscous liquid

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Traditional herbal medicinal product used for the relief of coughs, such as chesty, dry, tickly, irritating coughs and catarrh exclusively based on long standing use.

4.2 Posology and method of administration

For oral short-term use only.

Adults, the elderly and children over 12 years:
Using the measuring cup provided, 15 ml of syrup to be taken every 4 hours, 4 times per day. If required, up to a maximum of 6 doses (90 ml) can be taken per day.

Method of administration:
Buttercup Bronchostop Cough Syrup may be administered undiluted or diluted in water or warm tea.

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:
If symptoms worsen, or persist after 7 days, a doctor or a qualified Healthcare Professional should be consulted.

4.3 Contraindications

Hypersensitivity to the active substances, to other members of the *Lamiaceae* family or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Do not exceed the stated dose.

The use in children under 12 years of age is not recommended due to lack of data and because medical advice should be sought.

If symptoms worsen during use or do not improve after 1 week a qualified Healthcare Professional e.g. a doctor or pharmacist should be consulted.

If dyspnoea, fever or purulent sputum occurs, a doctor or qualified Healthcare Professional e.g. a doctor or pharmacist should be consulted.

Contains the preservatives methyl parahydroxybenzoate and propyl parahydroxybenzoate. These may cause hypersensitivity reactions, including delayed reactions.

Contains raspberry juice concentrate (which contains sucrose, glucose and fructose). Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Contains 4.61 g of xylitol which may have a laxative effect. Calorific value 2.4 kcal/g xylitol.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

The safety of the product during pregnancy and lactation has not been established. Therefore, in the absence of sufficient data, the 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 and to use machines have been performed.

4.8 Undesirable effects

Acute hypersensitivity reactions (including anaphylactoid reactions, such as oromucosal swelling, Quincke's oedema, dyspnoea, pruritus, rash and anaphylactic shock) have been reported in association with use of medicinal products containing thyme, in some cases, in patients with a history of allergy/asthma. Gastrointestinal disorders including nausea and vomiting have also been reported. The frequency of occurrence of these reactions is not known.

If these or other adverse reactions not mentioned above occur, a qualified Healthcare Professional e.g. a doctor or pharmacist 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

No cases of overdose have been reported.

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 genotoxicity have been performed with several thyme herb extracts and thyme essential oil as well as with a marshmallow root dry extract. No mutagenicity was observed in the Ames tests conducted.

Tests on reproductive toxicity and carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Herbal Preparations:
Maltodextrin
Acacia
Xylitol (E967)
Methyl Parahydroxybenzoate (E218)
Purified Water

Syrup:
Raspberry juice concentrate (containing sucrose, glucose and fructose)
Xylitol (E967)
Xanthan Gum
Citric Acid Monohydrate
Methyl Parahydroxybenzoate (E218)
Propyl Parahydroxybenzoate (E216)
Raspberry flavour
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years
After first opening: 4 weeks

6.4 Special precautions for storage

Do not store above 25°C. Store the bottle in the original package in order to protect from light.

6.5 Nature and contents of container

Brown glass bottles with tamper evident ring, with nozzle and polyethylene screw cap.
Polypropylene measuring cup with 2.5 ml to 20 ml scale.

Pack sizes: 120 ml, 200 ml, 240 ml and 290 ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 REGISTRATION HOLDER

Kwizda Pharma GmbH
Effingergasse 21
1160 Vienna
Austria

8 REGISTRATION NUMBER(S)

TR2006/001/001

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first registration: 13 March 2015

10 DATE OF REVISION OF THE TEXT

January 2018