Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Buttercup Bronchostop Cough Syrup

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

15 ml of syrup (~15.45 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 0.83 g liquid extract from *Althaea officinalis* L. radix (marshmallow root) (DER 1:12-14) Extraction solvent: water.

Excipients with known effect:
15 ml of syrup contains 11.59 mg of methyl parahydroxybenzoate (E218), 6.18 mg of propyl parahydroxybenzoate (E216),approximately 130 mg of total sugars (which includes 66 mg of fructose) from raspberry juice concentrate (containing sucrose, glucose and fructose) and 33.3 mg propylene glycol (E1520) contained in raspberry aroma flavour.

3 PHARMACEUTICAL FORM

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.

Buttercup Bronchostop Cough Syrup is indicated in adults and children aged 12 years and over.

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 persist, worsen or do not improve after 7 days use of Buttercup Bronchostop Cough Syrup, a qualified healthcare professional e.g. a doctor or pharmacist should be consulted.

4.3 Contraindications

Hypersensitivity to marshmallow root, thyme, to other members of the *Lamiaceae* (mint) 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.

Rare cases of hypersensitivity reactions, including severe reactions with angioedema, dyspnoea and shock that might require emergency care, have been observed following the use of products containing thyme. Treatment should be discontinued at the first sign of hypersensitivity (see also section 4.8 Undesirable effects).

Patients with a history of asthma or allergic reactions may have an increased risk of hypersensitivity reactions that may also be severe. These patients should consult with a doctor before using this product.

Absorption of concomitantly administered medicines may be delayed. As a precautionary measure, the product should not be taken ½ to 1 hour before or after intake of other medicinal products.

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

Each 15 ml dose of this medicine contains approximately 130 mg of total sugars (which includes 66 mg of fructose) from raspberry juice concentrate (which contains sucrose, glucose and fructose). Patients with rare hereditary problems of fructose intolerance (HFI), glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.
The additive effect of concomitantly administered products containing fructose (or sorbitol) and dietary intake of fructose (or sorbitol) should be taken into account.

This medicine contains 4.61 g of xylitol in each 15 ml dose which may have a laxative effect. Calorific value 2.4 kcal/g xylitol.

This medicine contains 33.3 mg of propylene glycol (E1520), from raspberry aroma flavour, in each 15 ml dose.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

Absorption of concomitantly administered medicines may be delayed. As a precautionary measure, the product should not be taken ½ to 1 hour before or after intake of other medicinal products.

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

Tabulated list of adverse reactions
The following table displays adverse reactions that have been reported with the use of the medicinal product from post-marketing experiences.

Undesirable effects are listed by body system and frequency using the following convention:
Very common (≥1/10), common (≥1/100, <1/10) uncommon (≥1/1.000, <1/100), rare (≥1/10.000, <1/1.000), very rare (<1/10.000), not known (cannot be estimated from the available data).

MedDRA System organ class	**Undesirable Effects**	**Frequency**
Immune system disorders	Anaphylactic reaction, hypersensitivity (including angioedema, dyspnoea and shock) (see also section 4.4)	Not known
Gastrointestinal disorders	Nausea, vomiting, diarrhoea, abdominal discomfort, abdominal pain, gastrointestinal disorder	Not known
Skin and subcutaneous tissue disorders	Rash, urticaria, pruritus	Not known

Undesirable effects listed under the SOCs *Gastrointestinal disorders* and *Skin and subcutaneous tissue disorders* can also occur as symptoms of hypersensitivity.
If 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 the national reporting system: HPRA Pharmacovigilance Website: www.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

Syrup:

Raspberry juice concentrate (containing sucrose, glucose and fructose)
Xylitol (E967)
Xanthan Gum
Citric Acid Monohydrate
Methyl Parahydroxybenzoate (E218)
Propyl Parahydroxybenzoate (E216)
Raspberry aroma flavour (synthetic and natural flavourings, propylene glycol (E1520))
Glycerol (E422)
Saccharin-sodium (E954)
Neohesperidin-dihydrochalcone
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, 200ml, 240 ml and 290 ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Kwizda Pharma GmbH
Effingergasse 21
Vienna
1160
Austria

7 REGISTRATION HOLDER

Kwizda Pharma GmbH
Effingergasse 21
Vienna
1160
Austria

8 MARKETING AUTHORISATION NUMBER

TR2006/001/001

8 REGISTRATION NUMBER(S)

TR2006/001/001

9 DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

Date of first registration: 13th March 2015
Date of last renewal: 12th March 2020

10 DATE OF REVISION OF THE TEXT

January 2023