Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Buttercup Bronchostop Berry Flavour Cough Pastilles

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each pastille contains:

59.5 mg of dry extract from *Thymus vulgaris* L. and *Thymus zygis* L. herba (thyme herb) (7-13:1). Extraction solvent: water

Excipients with known effect:
Each pastille contains 523 mg sorbitol (E420), 300 mg fructose, 5.53 mg propylene-glycol (E1520) which is contained in the aronia and fruit of the forest flavours, 0.0018 mg benzyl-alcohol (E1519) which is contained in the fruit of the forest flavour and 0.224 mg of sodium.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Pastille.

Hexagonal, brown pastilles with a fruity taste.

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 Berry Flavour Pastilles are indicated in adults and children aged 12 years and over.

4.2 Posology and method of administration

Posology:

For oral short-term use only.

Adults, the elderly and children over 12 years:
1-2 pastilles to be taken every 4 hours, 4 times a day. If required, up to a maximum of 12 pastilles can be taken per day.

Method of administration:

For oral use (allow to dissolve in the mouth through sucking).

This product is not recommended for use in children under 12 years of age (See Section 4.4)

Duration of use:

If symptoms persist, worsen or do not improve after 7 days use of Buttercup Bronchostop Berry Flavour Pastilles, a qualified healthcare professional e.g a doctor or pharmacist should be consulted.

4.3 Contraindications

Hypersensitivity to thyme or 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, or persist after 7 days, a doctor or qualified Healthcare Professional should be consulted.

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

This medicine contains 523 mg of sorbitol and 300 mg of fructose per pastille. Patients with hereditary fructose intolerance (HFI) should not take this medicinal product. The additive effect of concomitantly administered products containing fructose or sorbitol and dietary intake of fructose or sorbitol should be taken into account. The content of sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use administered concomitantly.

This medicine contains 5.53 mg of propylene-glycol per pastille.

This medicine contains 0.0018 mg benzyl-alcohol (E1519) in each pastille. Benzyl-alcohol (E1519) may cause allergic reactions. High volumes should be used with caution and only if necessary, especially in subjects with liver or kidney impairment because of the risk of accumulation and toxicity (metabolic acidosis).

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

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.

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, 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

The following table displays undesirable effects that have been reported from post-marketing experiences.

Undesirable effects are listed by MedDRA system organ class and frequency using the following convention:
Very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1,000 to < 1/100); rare (≥ 1/10,000 to <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 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 the national reporting system: HPRA Pharmacovigilance Website: www.hpra.ie

4.9 Overdose

No case of overdose has 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 different thyme herb extracts and thyme essential oil. 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 Preparation:
Maltodextrin
Acacia (arabic gum) (E414)

Pastille:
Acacia (arabic gum) (E414)
Fructose
Sorbitol liquid non-crystallising (E420)
Citric acid anhydrous (E330)
Saccharin sodium (E954)
Aronia flavour (which contains propylene-glycol (E1520))
Fruit of the forest flavour (which contains propylene-glycol (E1520) and benzyl-alcohol (E1519))
Paraffin light liquid
Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 30°C. Store the blister in the original package in order to protect from light.

6.5 Nature and contents of container

PVC/PE/PVdC/Alu blister packs with 10, 20 or 40 pastilles.

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
1160 Vienna
Austria

8 MARKETING AUTHORISATION NUMBER

TR2006/001/002

8 REGISTRATION NUMBER(S)

TR2006/001/002

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

December 2024