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 300 mg fructose and 523 mg sorbitol (E 420)

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.

4.2 Posology and method of administration

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 Special warnings and precautions for use.’)

Duration of use:

If symptoms worsen, or persist after 7 days, a doctor or 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* 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.

Contains 0.6 g of fructose per maximum single dose (2 pastilles). This should be taken into account in patients with diabetes mellitus.

Contains fructose and sorbitol. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

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

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 product 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 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 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

Pastille:
Acacia
Fructose
Sorbitol (E420)
Anhydrous Citric Acid
Saccharin Sodium
Aronia (chokeberry) aroma flavour
Fruit of the forest (berry) aroma flavour
Light Liquid Paraffin
White Beeswax
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 REGISTRATION HOLDER

Kwizda Pharma GmbH
Effingergasse 21
1160 Vienna
Austria

8 REGISTRATION NUMBER(S)

TR2006/001/002

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