Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Buttercup Bronchostop Day & Night Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 15 ml (= 16.3 g) of oral solution contains:

187.5 mg of extract (as dry extract) from *Althaea officinalis* L., radix (Marshmallow root) (7- 9:1). Extraction solvent: water
136.4 mg of extract (as dry extract) from *Tilia cordata* Miller, *Tilia platyphyllos* Scop., *Tilia* x *europaea* L. or their mixtures, flos (Lime flower) (3-8:1). Extraction solvent: water
150.0 mg of extract (as dry extract) from *Plantago lanceolata* L., folium (Ribwort plantain leaf) (4-6:1). Extraction solvent: water

Excipients with known effect:
Each 15 ml of oral solution contains 2.76 g xylitol (E967), 11.3 mg methyl- parahydroxybenzoate (E 218), 6.6 mg propyl parahydroxybenzoate (E216) and strawberry flavour (containing 13.6 mg propylene-glycol and 0.0018 mg benzyl-alcohol)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution.
Brown opaque liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Traditional herbal medicinal product used in adults and adolescents aged 12 years and older for the symptomatic treatment of throat irritation and dry cough, associated with common cold. The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.

4.2 Posology and method of administration

Start at the first sign of the common cold (throat irritation and dry cough).

Posology
Adults and adolescents aged 12 years and above:
Using the measuring cup provided, 15 ml of oral solution should be taken as required up to four times daily (the maximum recommended dose is 60 ml in 24 hours). The last dose should be taken directly before bedtime.

Paediatric population
Children under 12 years:
The use in children under 12 years of age is not recommended.

Method of administration
For oral use (undiluted).

Due to the partly physical and local mode of action of the medicinal product, it is recommended to refrain from drinking for 30 minutes to 1 hour after intake.

Duration of use
If the symptoms persist, worsen or do not improve after 7 days use of Buttercup Bronchostop Day & Night oral solution, a doctor should be consulted.

For oral short term use only.

4.3 Contraindications

Hypersensitivity to marshmallow root, lime flower, ribwort plantain 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.

If the symptoms worsen during the use of the medicinal product or if dyspnoea, high fever or purulent sputum occurs, a doctor should be consulted.

Absorption of concomitantly administered medicines may be delayed. As a precautionary measure, this medicinal product should not be taken 30 minutes to 1 hour before or after taking other medicines (see also section 4.5)

The medicine contains 11.04 g of xylitol in the maximum daily dose (60 ml), which may have a laxative effect. Calorific value 2.4 kcal/g xylitol.

The medicinal product contains the preservatives methyl-parahydroxybenzoate and propyl- parahydroxybenzoate. These may cause allergic reactions (possibly delayed).

This medicine contains 13.6 mg of propylene glycol in each 15 ml.

The medicine contains 0.0018 mg benzyl alcohol in each 15 ml dose. Benzyl alcohol 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).

Paediatric population
The use in children under 12 years of age has not been established due to lack of adequate data.

4.5 Interaction with other medicinal products and other forms of interactions

No interaction studies have been performed.

Due to the sedative activity of lime flower, Buttercup Bronchostop Day & Night oral solution may potentiate the sedation induced by CNS depressants such as antihistamines, antidepressants, benzodiazepines, opioids and alcohol (see section 4.4.)

Theoretically, mucilage present in all three active herbal ingredients may delay the absorption of concomitantly administered drugs (see section 4.4).

4.6 Fertility, pregnancy and lactation

Pregnancy and breast-feeding

The safety of the product during pregnancy and lactation has not been established.

Pregnancy
There are no or limited amount of data from the use of marshmallow root dry extract, lime flower dry extract and ribwort plantain leaf dry extract in pregnant women. Animal studies are insufficient with respect to developmental toxicity. Buttercup Bronchostop Day & Night Oral Solution is not recommended during pregnancy and in women of childbearing potential not using contraception.

Lactation
It is unknown whether components of marshmallow root dry extract, lime flower dry extract and ribwort plantain leaf dry extract are excreted in human milk. There is insufficient information on the excretion in animal milk. A risk to the suckling child cannot be excluded.
A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Buttercup Bronchostop Day & Night Oral Solution therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

Fertility
No human data on fertility of marshmallow root dry extract, lime flower dry extract and ribwort plantain leaf dry extract are available. Animal studies are insufficient with regard to reproductive toxicity.

4.7 Effects on ability to drive and use machines

No studies on the ability to drive and use machines have been performed. Due to the mild sedative activity of lime flower, this product may cause drowsiness. If affected, individuals should not drive or operate machinery.

4.8 Undesirable effects

None known.

If adverse reactions occur, 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
Website: www.hpra.ie

4.9 Overdose

No cases of overdose have been reported.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: other cold preparations, ATC code: R05X

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

In tests on genotoxicity (Ames tests) with marshmallow root dry extract, lime flower dry extract and ribwort plantain leaf dry extract no mutagenicity was observed with and without metabolic activation.

Tests on developmental and reproductive toxicity and carcinogenicity have not been performed.

Non-clinical data reveal no special hazard for humans when Buttercup Bronchostop Day & Night Oral Solution is used as indicated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Excipients of the herbal preparations:
Maltodextrin,
Silica, colloidal anhydrous

Excipients of the herbal product:
Xylitol (E967),

Glycerol,
Citric acid monohydrate,
Xanthan gum,
Methyl-parahydroxybenzoate (E218),
Propyl-parahydroxybenzoate (E216),
Strawberry flavour (containing propylene-glycol (E1520) and benzyl-alcohol),
Water, purified

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.
Keep the container tightly closed after use.

6.5 Nature and contents of container

Brown glass bottles with a nozzle and plastic screw cap packed in a carton box. A plastic cup with a scale from 2.5 ml to 20 ml for measuring the recommended dose is provided.

Pack sizes: 120 ml, 200 ml and 240 ml
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 REGISTRATION HOLDER

Kwizda Pharma GmbH
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Vienna
1160
Austria

8 REGISTRATION NUMBER(S)

TR2006/002/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26th February 2021

10 DATE OF REVISION OF THE TEXT

June 2022