

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Sanderson's Throat Specific Mixture

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:

0.025 ml of Capsicum Tincture (*Capsicum annuum* L. var. *minimum* (Miller) Heiser), corresponding to 7.5 to 12.5 micrograms capsaicinoids calculated as capsaicin. Extraction solvent: ethanol 90% v/v.

0.025 ml of extract (as liquid extract) from Squill bulb (*Drimia maritima* (L.) Stearn) (1:1). Extraction solvent: ethanol 65% v/v.

37.5 mg of Acetic acid

Each 5 ml contains 62.66 mg of ethanol (see section 4.4 'Special warnings and precautions for use').

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Mixture

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For symptomatic relief of sore throat, hoarseness, loss of voice and catarrh, and as a preventative gargle when these symptoms begin to appear or are expected to appear.

Sanderson's Throat Specific Mixture is indicated in adults and children aged 8 years and over.

4.2 Posology and method of administration

Posology

Adults, the elderly and children over 8 years

Gargle with 10 ml (two 5 ml spoonfuls) in an equal amount of water hourly. Also swallow slowly one 5 ml spoonful undiluted, three times daily.

If symptoms of sore throat, hoarseness, loss of voice or catarrh are expected to appear, gargle well with 10 ml (two 5 ml spoonfuls) in twice the amount of water in the morning before breakfast and last thing at night.

Do not use for more than 7 consecutive days (see section 4.4)

Paediatric population

Not recommended for children under 8 years of age.

Method of administration

For oral and oromucosal use.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

Cardio-pulmonary disorders or breathing difficulties.

History of alcohol abuse, liver disease or renal impairment.

Raised intracranial pressure.

4.4 Special warnings and precautions for use

This product contains small amounts of alcohol (less than 100 mg per 5 ml dose).

This product has a sharp biting taste.

If symptoms worsen or persist after 7 days, a doctor should be consulted.

Patients should be advised not to exceed the stated dose.

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

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

In view of the potential for squill to interact with other medicines administered concurrently, the product should not be taken with digoxin or any medicine for a heart condition.

Contains alcohol and should be avoided in patients taking other medicines known to interact with alcohol (e.g. metronidazole).

4.6 Fertility, pregnancy and lactation

The safety of this product during pregnancy and lactation has not been established, therefore use during pregnancy and lactation is not recommended.

No studies on the effects on fertility have been performed.

4.7 Effects on ability to drive and use machines

No studies on the effect on the ability to drive or use machines have been performed.

This product contains alcohol (see section 4.4).

4.8 Undesirable effects

Hypersensitivity.

Squill is reported to cause gastric irritation. The frequency is not known.

Reporting of 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 Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

4.9. Overdose

No specific problem anticipated

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic Properties

None applicable.

5.2. Pharmacokinetic Properties

None applicable.

5.3. Pre-clinical Safety Data

None applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Quassia liquid extract

Benzoic acid

Caramel

Ethanol 96%

Saccharin sodium

Purified water

6.2. Incompatibilities

None known.

6.3 Shelf life

5 years.

6.4. Special Precautions for Storage

Store in a cool place.

6.5 Nature and contents of container

Bottle of 100 ml or 200 ml.

Glass bottle, cap- PP28 Clicloc tamper evident assembly with a PVdC coated wad liner.

6.6 Special precautions for disposal

No special requirements for disposal.

7 MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

PL 0415/5000R

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

07 May 1992 / 24 June 1997

10 DATE OF REVISION OF THE TEXT

25/07/2017