

## **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](http://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 Preclinical 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**

Clear, round, Type III glass bottles, each containing 200 ml.  
White HDPE/PP tamper-evident, child-resistant caps with EPE liners.

#### **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 19664/0002

### **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

07 May 1992 / 24 June 1997

### **10 DATE OF REVISION OF THE TEXT**

27/06/2023