

## **1. NAME OF THE MEDICINAL PRODUCT**

Kestrel Dry Throat Relief Pastilles

## **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Levomenthol	1.07% w/w
Peppermint Oil	0.54% w/w
Myrrh Tincture	1.39% v/w

## **3 PHARMACEUTICAL FORM**

Pastille

## **4 CLINICAL PARTICULARS**

### **4.1 Therapeutic indications**

Relief of irritations due to excessive speaking, singing or smoking. Aid in soothing dry irritated throats which so often accompany the common cold.

### **4.2 Posology and method of administration**

Adults, elderly and children over 12 years:-

Dissolve one pastille in the mouth and inhale deeply. Repeat every two hours if required.

Oral administration

### **4.3 Contraindications**

Hypersensitivity to menthol, peppermint, myrrh (*Commiphora*) or any of the other ingredients

### **4.4 Special warnings and precautions for use**

Keep out of the sight and reach of children.

If symptoms persist, consult your doctor.

Contains sucrose and glucose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

None known

#### **4.6 Pregnancy and lactation**

##### *Pregnancy*

There is no or inadequate evidence of the safety of menthol, peppermint oil or myrrh tincture in human pregnancy. The potential risk for humans is unknown.

Caution should be exercised when prescribing to pregnant women.

##### *Lactation*

It is not known whether the active ingredients of Vocalzone Throat Pastilles are excreted in human breast milk.

#### **4.7 Effects on ability to drive and use machines**

None known

#### **4.8 Undesirable effects**

Hypersensitivity reactions including anaphylaxis, angioedema, urticaria, bronchospasm/asthma, dyspnoea and rash have been reported very rarely with menthol-containing preparations.

#### **Reporting of Side Effects**

If you get any side effects, talk to your dentist, doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the Yellow Card Scheme at:

[www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

#### **4.9 Overdose**

Symptoms of overdose are unlikely unless the product is taken grossly in excess of the recommended dose.

Treatment of symptoms and general supportive measures are recommended in case of acute overdose.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Soothing and astringent to mucous membranes

### **5.2 Pharmacokinetic properties**

Not applicable

### **5.3 Preclinical safety data**

None

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Sucrose

Glucose, Liquid

Modified Starch (Tapioca, Maize)

Vegetable Oil

Carnauba Wax

Colour E153 (Vegetable Carbon Black, Glucose Syrup, Sodium Benzoate E211)

Liquorice Extract

Purified Water

### **6.2 Incompatibilities**

None known

### **6.3 Shelf life**

36 months as packaged for sale

### **6.4 Special precautions for storage**

Store below 25°C.

### **6.5 Nature and contents of container**

24 pastilles packed in blisters of 250 µ PVC & 20 µ aluminium foil.

### **6.6 Special precautions for disposal**

Not applicable

**7      MARKETING AUTHORISATION HOLDER**

Kestrel Medical Limited

Kestrel House

7 Moor Road

Broadstone

Dorset

BH18 8AZ

United Kingdom

**8      MARKETING AUTHORISATION NUMBER(S)**

PL 18955/0001

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

26<sup>th</sup> October 2001

**10     DATE OF REVISION OF THE TEXT**

06/03/2018