

## **PRODUCT SUMMARY**

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

Eskornade Syrup.

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each 5 ml of syrup contains Phenylpropanolamine Hydrochloride BP 12.5 mg and Diphenylpyraline Hydrochloride BP 1.5 mg.

### **3. PHARMACEUTICAL FORM**

Syrup.

## **4. CLINICAL PARTICULARS**

### **4.1. Therapeutic indications**

It is indicated in the relief of congestion and hyper-secretion in the nasal cavity and paranasal sinuses, associated with the common cold, allergic rhinitis, acute and chronic rhinitis, sinusitis and influenza.

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

The stated dose should not be exceeded.

*Adults:* Two 5 ml doses up to four times a day.

*Elderly:* Use with great caution.

*Children:* Aged 2 to 5 years old: One 2.5 ml dose up to four times a day.

Aged 6 to 12 years old: One 5 ml dose up to four times a day.

Not recommended for children under 2 years old.

Route of Administration: Oral.

### **4.3. Contra-indications**

Do not use in patients with hypertensive disease, including those treated with antihypertensive drugs, whose action may be impaired by phenylpropanolamine, heart disease or hyperthyroidism; or hypersensitivity to either of the ingredients; or during, or for 14 days after treatment with a monoamine oxidase inhibitor.

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

Patients who drive or operate machinery should be warned of the possibility of drowsiness. Alcoholic drinks should be avoided. Administer with caution to patients with organic heart disease or angina of effort or with prostatic hypertrophy or glaucoma. Potentiation may occur if this product is used with other CNS depressants. Eskornade should be used with caution in patients with diabetes mellitus. The recommended dose must not be exceeded. In the event of an overdose, medical attention should be sought immediately.

#### **4.5. Interactions with other medicinal products and other forms of interaction**

None stated.

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

Eskornade has been available since 1960. Based on animal studies and clinical experience, there is no evidence to suggest any associated hazard to the foetus. Nevertheless, drugs should be avoided in pregnancy unless essential, especially during the first trimester.

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

Patients who drive or operate machinery should be warned of the possibility of drowsiness.

#### **4.8. Undesirable effects**

Blurred vision, dry mouth, urinary hesitancy or retention, palpitations, drowsiness or insomnia, and dizziness may occur. Headache, anxiety, agitation and insomnia can occur at recommended doses. Elevated blood pressure may occur although this has rarely been reported at recommended doses.

#### **4.9. Overdose**

Signs and symptoms may be related to either of the product's constituents and may include nausea and vomiting, irritability, convulsions, fever, tachycardia, arrhythmias or increased blood pressure. Psychosis, hallucinations, confusion, depression, and cerebrovascular bleeding, possibly associated with hypertensive crisis are rare reactions in overdose. Treatment of overdose consists of either gastric lavage or ipecacuanha followed by activated charcoal. A further dose of activated charcoal should be considered together with appropriate supportive and symptomatic measures. Central excitation or convulsions may require treatment with diazepam.

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1. Pharmacodynamic properties**

Eskomade is a combination of an oral nasal decongestant and an antihistamine (H1-receptor antagonist).

## **5.2. Pharmacokinetic properties**

Phenylpropanolamine hydrochloride is readily and completely absorbed from the gastrointestinal tract and is excreted mainly unchanged in the urine.

It is used in doses of up to 25 mg, 3 or 4 times daily, in the symptomatic treatment of nasal congestion.

Diphenylpyraline hydrochloride may be taken by mouth in a dose of up to 20 mg/day, in 3 or 4 divided doses, in the treatment of rhinitis.

## **5.3. Preclinical safety data**

No further data of relevance.

# **6. PHARMACEUTICAL PARTICULARS**

## **6.1. List of excipients**

Saccharin Sodium BP  
Sodium Dihydrogen Phosphate BP  
Methyl Parahydroxybenzoate EP  
Propyl Parahydroxybenzoate EP  
Glycerol EP  
Sorbitol Syrup 70% w/w BP  
Propylene Glycol EP  
Quinolone Yellow E1 04  
Greengage Flavour 51005 9E  
Purified Water EP  
Green S E142

## **6.2. Incompatibilities**

None stated.

## **6.3. Shelf life**

36 months.

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

Store below 25 °C. Do not refrigerate.

**6.5. Nature and contents of container**

Amber PET bottles (polyethylene terephthalate) containing 100 or 150 ml of syrup or amber clear glass bottles containing 100 or 150 ml syrup.

**6.6. Instructions for use/handling**

None.

**ADMINISTRATION DATA**

**7. MARKETING AUTHORISATION HOLDER**

Goldshield Group Plc  
Trading as Goldshield Pharmaceuticals  
NLA Tower  
Croydon  
CR0 OXT.

**8. MARKETING AUTHORISATION NUMBER(S)**

PL 10972/0021

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

16 March 1994

**10. DATE OF (PARTIAL) REVISION OF THE TEXT**

November 2003