



SUMMARY OF PRODUCT CHARACTERISTICS

PRODUCT SUMMARY

1. NAME OF THE MEDICINAL PRODUCT

Eskornade Spansule Capsules.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Spansule capsule contains Phenylpropanolamine Hydrochloride BP 50 mg and Diphenylpyraline Hydrochloride BP 5 mg.

3. PHARMACEUTICAL FORM

Sustained release capsule.

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.

<i>Adults</i>	One Eskornade Spansule capsule every 12 hours
<i>Elderly</i>	Use with great caution.
<i>Children</i>	Not recommended in children under the age of 12 years.

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 Spansule Capsules 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. Absorption of phenylpropanolamine and diphenylpyraline from the sustained-release Spansule capsule is likely to be prolonged and this should be borne in mind. 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**

Eskornade is a combination of a sympathomimetic agent(phenylpropanolamine) and a H1-receptor antagonist (diphenylpyraline) which, when given orally, gives symptomatic relief from nasal congestion and rhinitis.

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

Sucrose (granulated sugar) EP
Sucrose (caster sugar) EP
Maize starch EP
Heavy kaolin EP
Talc EP
Gelatin BP
Glyceryl Distearate
Microcrystalline Wax
Dioctyl Sodium Sulphosuccinate BPC
Povidone 30 (polyvinylpyrrolidone K30) BP
Red Iron Oxide
Vegetable Carbon Black 14368 E153
Hydrochloric acid EP
Industrial Methylated Spirit 99
Carbon Tetrachloride (Technical)
Purified Water EP

Hard gelatin capsule:
Black Iron Oxide
Titanium Dioxide
Gelatin BP

6.2. Incompatibilities

None stated.

6.3. Shelf life

24 months.

6.4. Special precautions for storage

Store in a dry place at a temperature not exceeding 25 °C

6.5. Nature and contents of container

Securitainers, amber glass bottles, polythene vials each containing 30 capsules
Blister packs of 6, 12, 24 or 30 capsules.

6.6. Instructions for use/handling

None

ADMINISTRATION DATA

7. MARKETING AUTHORISATION HOLDER

Goldshield Group Plc
Trading as Goldshield Pharmaceuticals
NLA Tower
Croydon
CR0 OXI

8. MARKETING AUTHORISATION NUMBER(S)

PL 10972/0020

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21 April 1994

10. DATE OF (PARTIAL) REVISION OF THE TEXT

November 2003