Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Iliadin 0.05% w/v Nasal Spray, Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Oxymetazoline Hydrochloride 0.05% w/v.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Nasal spray, solution
A clear, colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the relief of nasal congestion associated with disorder of the upper respiratory tract including infective and allergic rhinitis, sinusitis, nasopharyngitis and coryza.

4.2 Posology and method of administration

Adults and children over 6 years

One spray into each nostril every 8-12 hours.

Intranasally.

4.3 Contraindications

Use in patients with known hypersensitivity to sympathomimetics.

Use in patients receiving monoamine oxidase inhibitors or within fourteen days of stopping such treatment.

Use in acute coronary disease, cardiac asthma, thyrotoxicosis, hypertension, closed-angle glaucoma or urinary retention.

Use in children under 6 years of age.

4.4 Special warnings and precautions for use

Use with great care in patients suffering from angina and digitalized patients.

This product should be given with care to patients with prostatic enlargement, as it may increase difficulty in micturition.

Prolonged use may cause rebound congestion and drug induced rhinitis.

Use with caution in diabetic patients as this product may cause an increase in blood sugar.

The physician or pharmacist should reassure himself/herself that sympathomimetic containing preparations are not simultaneously administered by several routes i.e. orally and topically (nasal, aural and eye preparations).

This product should not be used for more than 5-7 consecutive days without medical advice.

Care should be taken not to exceed the stated dose.

This product should not be used by patients already taking medication without first consulting their physician.

This product may act as a cerebral stimulant giving rise to insomnia, nervousness, hyperpyrexia, tremor and epileptiform convulsions.

4.5 Interaction with other medicinal products and other forms of interaction

Concurrent use with halogenated anaesthetic agents may provoke or worsen ventricular arrhythmias.

The effects of this product may be altered by guanethidine, reserpine, methyldopa, phenothiazines and tricyclic anti depressants.

4.6 Pregnancy and lactation

Iliadin should not be used in pregnancy unless considered essential by the physician.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Side effects include local stinging, irritation and dryness.
Prolonged use may cause rebound vasodilation and chemical rhinitis.

4.9 Overdose

No experience of overdose, but supportive measures would be the appropriate treatment.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Oxymetazoline is a potent sympathomimetic agent which has at least ten times the potency of xylometazoline, a greater therapeutic index and greater duration of action. Acute toxicity studies in mice have indicated no unusual aspects of lethality.

5.2 Pharmacokinetic properties

Tritiated oxymetazoline has been shown to be rapidly absorbed in dogs following intranasal administration. Approximately 30% is excreted in the urine within 72 hours and faecal excretion is about 10% within 120 hours. The drug is approximately 30% bound to human plasma proteins.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already updated in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Dihydrogen Phosphate Dihydrate
Disodium Phosphate Dodecahydrate
Sodium Hydroxide
Water for injection

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

Unopened: 2 years.

After first opening the container: 28 days.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

15ml spray bottles manufactured from polypropylene with an inner polyethylene film container with a polythene plug pierced with a polythene capillary tube and containing a clear colourless solution.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Seven Seas Limited
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Merck Consumer Health
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8 MARKETING AUTHORISATION NUMBER

PA 417/12/4

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