Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Iliadin 0.05% w/v Nasal Drops, Solution.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Oxymetazoline Hydrochloride 0.05% w/v.

For excipients, see 6.1

3 PHARMACEUTICAL FORM

Nasal drops, solution.

A clear, colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

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

4.2 Posology and method of adminstration

Adults and children over the age of 6 years.

2-3 drops into each nostril every 8 to 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 special 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 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.

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 Drops 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 may include local stinging, irritation and dryness.
Prolonged use may cause rebound vasodilatation 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% are 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 Dihydrate
Benzalkonium Chloride Solution
Sodium Hydroxide
Water for injection.

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

Unopened: 3 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

10ml screw topped brown glass bottle with rubber teated standard dropper pipette incorporated into screw top and containing a clear colourless solution.

6.6 Instructions for use and handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA 417/12/1

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Date of last renewal: 1st April 2004

10 DATE OF REVISION OF THE TEXT

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