1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINE FOR HUMAN USE

FLONASE®

SCHEDULING STATUS:

S2

PROPRIETARY NAME AND DOSAGE FORM:

FLONASE® AQUEOUS NASAL SPRAY

Metered-dose nasal spray (suspension)

COMPOSITION:

FLONASE AQUEOUS NASAL SPRAY contains fluticasone propionate 0,05 % *m/m*. Each metered spray of 100 mg delivered by the nasal adaptor contains 50 µg of fluticasone propionate.

Preservatives: benzalkonium chloride 0,02 % *m/m*, phenylethyl alcohol 0,25 % *m/m*.

Excipients: microcrystalline cellulose and carboxymethylcellulose sodium, dextrose (anhydrous), diluted hydrochloric acid, polysorbate 80 and purified water.

PHARMACOLOGICAL CLASSIFICATION:

A 21.5.1 Corticosteroids and analogues

PHARMACOLOGICAL ACTION:

Pharmacodynamic properties:

Fluticasone propionate has anti-inflammatory activity.

Pharmacokinetic properties:

The terminal plasma half-life is approximately 3 hours. The apparent volume of distribution is approximately 260 litres.

INDICATIONS:

FLONASE AQUEOUS NASAL SPRAY is indicated for the short-term (less than 6 months) prophylaxis and treatment of symptoms of allergic rhinitis (hay fever) in adults and children over 12 years.

CONTRA-INDICATIONS:

FLONASE AQUEOUS NASAL SPRAY is contra-indicated in patients with a sensitivity to any of its ingredients.

WARNINGS AND SPECIAL PRECAUTIONS:

Infections of the nasal airways should be appropriately treated but do not constitute a specific contra-indication to treatment with FLONASE AQUEOUS NASAL SPRAY.

The full benefit of FLONASE AQUEOUS NASAL SPRAY may not be achieved until treatment has been administered for several days.

Care must be taken while transferring patients from systemic steroid treatment to FLONASE AQUEOUS NASAL SPRAY if there is any reason to suppose that their adrenal function is impaired.

FLONASE AQUEOUS NASAL SPRAY may cause hypothalamic-pituitary-adrenal (HPA) axis suppression following intranasal application at dosages

higher than recommended.

A heavy challenge of summer allergens may necessitate appropriate additional therapy, particularly to control eye symptoms.

PREGNANCY AND LACTATION:

Safety during pregnancy and lactation has not been established. Corticosteroids have been shown to be teratogenic in animals. As these agents may be absorbed systemically when administered intra-nasally, teratogenicity cannot be excluded.

DOSAGE AND DIRECTIONS FOR USE:

Shake gently before use.

FLONASE AQUEOUS NASAL SPRAY is for administration by the intranasal route only.

For full therapeutic benefit regular usage is essential. The absence of an immediate effect should be explained to the patient as maximum relief may not be obtained until after 3 to 4 days of treatment.

Adults and children over 12 years of age:

For the prophylaxis and treatment of allergic rhinitis (hay fever):

Two sprays into each nostril once a day, preferably in the morning.

Elderly:

The normal adult dose is applicable.

SIDE EFFECTS:

Clinical Trial Data:

Adverse events are listed below by system organ class and frequency. Frequencies are defined as: very common (≥ 1/10), common (≥ 1/100 and < 1/10), uncommon (≥ 1/1 000 and < 1/100), rare (≥ 1/10 000 and < 1/1 000) and very rare (< 1/10 000) including isolated reports.

Nervous system disorders:

Common: unpleasant taste, unpleasant smell

Respiratory, thoracic and mediastinal disorders:

Very common: epistaxis.

Common: nasal dryness, nasal irritation, throat dryness, throat irritation.

Post-marketing Data:

Immune system disorders: hypersensitivity reactions, skin rash, oedema of the face or tongue

Respiratory, thoracic and mediastinal disorders: nasal septal perforation.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See SIDE EFFECTS.

Chronic: Administration of fluticasone propionate in daily doses in excess of that recommended, or in conjunction with other corticosteroid formulations, may lead to some degree of suppression of hypothalamic-pituitary-adrenal function. Monitoring of adrenal reserve may be indicated.

Further treatment is symptomatic and supportive.

IDENTIFICATION:

A white, opaque suspension.

PRESENTATION:

FLONASE AQUEOUS NASAL SPRAY is supplied in a white plastic bottle fitted with a metering, atomising pump, nasal adaptor and a dust cover. Each bottle provides approximately 120 metered sprays, when used as recommended.

STORAGE INSTRUCTIONS:

Store below 30 °C.

Protect from light.

Keep out of reach of children.

REGISTRATION NUMBER:

36/21.5.1/0504

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

DATE OF PUBLICATION OF THE PACKAGE INSERT:

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