FLIXONASE AQUEOUS NASAL SPRAY

SCHEDULING STATUS:

S3

PROPRIETARY NAME AND DOSAGE FORM:

FLIXONASE AQUEOUS NASAL SPRAY

Metered-dose nasal spray (suspension)

COMPOSITION:

FLIXONASE 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 volume of distribution is approximately 260 litres.

INDICATIONS:

FLIXONASE AQUEOUS NASAL SPRAY is indicated for the prophylaxis and treatment of seasonal and perennial allergic rhinitis including hay fever in adults and the short term treatment of seasonal allergic rhinitis in children 4 - 11 years old.

CONTRA-INDICATIONS:

FLIXONASE 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 FLIXONASE AQUEOUS NASAL SPRAY.

The full benefit of FLIXONASE 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 FLIXONASE AQUEOUS NASAL SPRAY if there is any reason to suppose that their adrenal function is impaired.

FLIXONASE 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.

INTERACTIONS:

Care should be taken when co-administering known strong CYP3A4 inhibitors, e.g., ritonavir and ketoconazole, as there is potential for increased systemic exposure to fluticasone propionate.

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 intranasally, teratogenicity cannot be excluded.

DOSAGE AND DIRECTIONS FOR USE:

Shake gently before use.

FLIXONASE 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 seasonal and perennial allergic rhinitis: Two sprays into each nostril once a day, preferably in the morning. In some cases two sprays into each nostril twice daily may be required. The maximum daily dose should not exceed two sprays twice daily into each nostril.

Elderly: The normal adult dose is applicable.

Children under 12 years of age: For the prophylaxis and treatment of seasonal allergic rhinitis in children aged 4 - 11 years a dose of one spray into each nostril once daily is

recommended. The maximum daily dose should not exceed two sprays into each nostril. Safety and efficacy has not been studied for periods longer than 4 weeks.

For the prophylaxis and treatment of perennial allergic rhinitis in children of this age (4 - 11 years), there are insufficient clinical data at present to recommend the use of FLIXONASE AQUEOUS NASAL SPRAY.

SIDE EFFECTS:

Dryness and irritation of the nose and throat, unpleasant taste and smell, headache and epistaxis have been reported.

Hypersensitivity reactions including skin rash and oedema of the face or tongue have been reported. There have also been less frequent reports of anaphylaxis/anaphylactic reactions and bronchospasm.

Extremely rare cases of nasal perforation have been reported following the use of intranasal corticosteroids.

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:

FLIXONASE 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 at or below 30 °C.

Protect from light.

Keep out of reach of children.

REGISTRATION NUMBER:

X/21.5.1/359

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

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

DATE OF PUBLICATION OF THE PACKAGE INSERT:

Date of registration: 27 June 1991

Date of most recent revision: 3 December 2001

Date compliant with Regulation 11: 30 October 2015

GDS01

MANUFACTURER:

GLAXO WELLCOME S.A., Avenida de Extremadura 3, 09400 Aranda de Duero, Burgos, Spain

Botswana: Reg No B9320720 S2

Malawi: Reg No PMPB/PL270/35 POM

Namibia: Reg No 12/21.5.1/0241 NS2

Zambia: Reg No 179/014 POM

SKEDULERINGSTATUS:

S3

EIENDOMSNAAM EN DOSEERVORM:

FLIXONASE AQUEOUS NASAL SPRAY

Afgemete dosis neussproei (suspensie)

SAMESTELLING:

FLIXONASE AQUEOUS NASAL SPRAY bevat flutikasoonpropionaat 0,05 % *m/m*.

Elke afgemete sproei van 100 mg wat deur die neusstuk vrygestel word, bevat 50 µg flutikasoonpropionaat.

Preserveermiddels: bensalkoniumchloried 0,02 % *m/m*, fenieletielalkohol 0,25 % *m/m*.

Mengmiddels: mikrokristallyne sellulose en natriumkarboksimetielsellulose, anhidriese dekstrose, verdunde soutsuur, polisorbaat 80 en gesuiwerde water.

FARMAKOLOGIESE KLASSIFIKASIE:

A 21.5.1 Kortikosteroïede en analoë.

FARMAKOLOGIESE WERKING:

Farmakodinamiese eienskappe:

Flutikasoonpropionaat besit anti-inflammatoriese aktiwiteit.

Farmakokinetiese eienskappe:

Die terminale plasmahalfleeftyd is ongeveer 3 uur. Die distribusievolume is ongeveer 260 liter.

INDIKASIES:

FLIXONASE AQUEOUS NASAL SPRAY is aangedui vir die profilakse en behandeling van seisoenale en aanhoudende allergiese rinitis, insluitende hooikoors, by volwassenes en die korttermynbehandeling van seisoenale allergiese rinitis by kinders 4 - 11 jaar oud.

KONTRA-INDIKASIES:

FLIXONASE AQUEOUS NASAL SPRAY is teenaangedui by pasiënte met 'n sensitiwiteit vir enige van die bestanddele.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS:

Infeksies van die neuslugweë behoort toepaslik behandel te word, maar dit dui nie op 'n spesifieke kontra-indikasie vir die behandeling met FLIXONASE AQUEOUS NASAL SPRAY nie.

Die volledige voordeel van FLIXONASE AQUEOUS NASAL SPRAY mag eers bereik word nadat behandeling etlike dae toegedien is.

Pasiënte moet met sorg oorgeplaas word vanaf sistemiese steroïede na behandeling met FLIXONASE AQUEOUS NASAL SPRAY as daar enige rede is om te glo dat hulle adrenale funksie verswak is.

FLIXONASE AQUEOUS NASAL SPRAY kan onderdrukking van die hipotalamiese pituïtêre adrenale as (HPA-as) veroorsaak, na intranasale gebruik, teen dosisse hoër as wat aanbeveel word.

Kontak met ’n groot hoeveelheid somerallergene kan toepaslike addisionele terapie noodsaak, veral om oogsimptome te beheer.

INTERAKSIES:

Sorg moet toegepas word indien bekende sterk CYP3A4 inhibeerders bv. ritonavir en ketakonasool, tegelykertyd toegedien word, aangesien die moontlikheid bestaan van verhoogte sistemiese blootstelling aan flutikasoonpropionaat.

SWANGERSKAP EN LAKTASIE:

Veiligheid tydens swangerskap en borsvoeding is nie vasgestel nie. Daar is reeds aangetoon dat kortikosteroïede teratogenies is by diere. Aangesien hierdie middels sistemies geabsorbeer word wanneer intranasaal toegedien word, kan teratogenisiteit nie uitgesluit word nie.

DOSIS EN GEBRUIKSAANWYSINGS:

Skud liggies voor gebruik.

FLIXONASE AQUEOUS NASAL SPRAY moet slegs deur die intranasale roete toegedien word.

Gereelde gebruik is noodsaaklik vir optimum terapeutiese voordeel. Die afwesigheid van ’n onmiddellike effek behoort aan die pasiënt verduidelik te word aangesien maksimum verligting eers na 3 tot 4 dae van behandeling verkry kan word.

Volwassenes en kinders ouer as 12 jaar: Vir die profilakse en behandeling van seisoenale en aanhoudende allergiese rinitis: Twee sproeie in beide neusholtes een keer per dag, verkieslik in die oggend. In sommige gevalle kan twee sproeie in

beide neusholtes twee keer per dag benodig word. Die maksimum daaglikse dosis behoort nie twee sproeie, twee keer per dag in beide neusholtes te oorskry nie.

Bejaardes: Die normale volwasse dosis is van toepassing.

Kinders jonger as 12 jaar: Vir die profilakse en behandeling van seisoenale allergiese rinitis by kinders van 4 - 11 jarige ouderdom word 'n dosis van een sproei in beide neusholtes een keer per dag aanbeveel. Die maksimum daaglikse dosis behoort nie twee sproeie in beide neusholtes te oorskry nie. Veiligheid en doeltreffendheid is nie bestudeer vir tydperke langer as 4 weke nie.

Daar is tans nie genoegsame kliniese data om die gebruik van FLIXONASE AQUEOUS NASAL SPRAY vir die profilakse en behandeling van aanhoudende allergiese rinitis by kinders van hierdie ouderdom (4 - 11 jaar) aan te beveel nie.

NEWE-EFFEKTE:

Droogheid en irritasie van die neus en keel, onaangename smaak en reuk, hoofpyn en epistakse is aangemeld.

Hipersensitiwiteitsreaksies insluitende veluitslag en edeem van die gesig of tong is reeds aangemeld. Anafilakse/anafilaktiese reaksies en brongospasma is ook minder gereeld aangemeld.

Uiters seldsame gevalle van neusperforasie is aangemeld na die gebruik van intranasale kortikosteroïede.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:

Sien NEWE-EFFEKTE.

Chronies - Toediening van hoër daaglikse dosisse flutikasoonpropionaat as wat aanbeveel word, of tesame met ander kortikosteroïed-formulasies, kan lei tot 'n

mate van onderdrukking van hipotalamiese pituïtêre adrenale funksie. Monitering van adrenale reserwe kan aanbeveel word.

Verdere behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE:

'n Wit, ondeurskynende suspensie.

AANBIEDING:

FLIXONASE AQUEOUS NASAL SPRAY word in 'n wit plastiese bottel wat met 'n atomiseerpomp wat afgemete dosisse vrystel, neusstuk en 'n stofdeksel gepas is, voorsien. Elke bottel lewer ongeveer 120 afgemete sproeie as dit gebruik word soos aanbeveel.

BERGINGSAANWYSINGS:

Bewaar by of benede 30 °C.

Beskerm teen lig.

Hou buite bereik van kinders.

REGISTRASIENOMMER:

X/21.5.1/359

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:

GlaxoSmithKline South Africa (Edms) Bpk

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DATUM VAN PUBLIKASIE VAN DIE VOUBILJET:

Datum van registrasie: 27 Junie 1991

Datum van mees onlangse hersiening: 3 Desember 2001

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