SCHEDULING STATUS

S3

1. NAME OF THE MEDICINE

FLIXONASE AQUEOUS NASAL SPRAY 50 µg/spray nasal spray, suspension

2. QUALITATIVE AND QUANTITATIVE 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*.

Excipient with known effect:

Benzalkonium chloride.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Nasal spray, suspension.

A white, opaque suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic 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.

4.2 Posology and method of administration

Posology

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.

4.3 Contraindications

FLIXONASE AQUEOUS NASAL SPRAY is contraindicated in patients with a hypersensitivity to fluticasone propionate or to any of the ingredients listed in section 6.1.

4.4 Special warnings and precautions for use

Infections of the nasal airways should be appropriately treated but do not constitute a specific contraindication 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.

Systemic effects with nasal corticosteroids have been reported, particularly at high doses prescribed for prolonged periods. These effects are much less likely to occur than with oral corticosteroids and may vary in individual patients and between different corticosteroid preparations.

Reduced growth velocity has been observed in children treated with intranasal corticosteroids. Therefore, children should be maintained on the lowest dose which achieves adequate symptom control.

During post-marketing use, there have been reports of clinically significant interactions in patients receiving FLIXONASE AQUEOUS NASAL SPRAY and ritonavir, resulting in

systemic corticosteroid effects including Cushing's syndrome and adrenal suppression. Therefore, concomitant use of FLIXONASE AQUEOUS NASAL SPRAY and ritonavir should be avoided, unless the potential benefit to the patient outweighs the risk of systemic corticosteroid side effects (see section 4.5).

Visual disturbance has been reported by patients using systemic and/or topical corticosteroids. If a patient has blurred vision or other visual disturbances, consider evaluation of possible causes which may include cataract, glaucoma or central serous chorioretinopathy.

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

FLIXONASE AQUEOUS NASAL SPRAY contains benzalkonium chloride (see section 6.1). Long-term use may cause oedema of the nasal mucosa.

4.5 Interaction with other medicines and other forms of interaction

Under normal circumstances, very low plasma concentrations of fluticasone propionate are achieved after intranasal dosing, due to extensive first pass metabolism and high systemic clearance mediated by cytochrome P450 3A4 in the gut and liver. Hence, clinically significant interactions mediated by fluticasone propionate are unlikely.

An interaction study in healthy subjects has shown that ritonavir (a highly potent cytochrome P450 3A4 inhibitor) can greatly increase fluticasone propionate plasma concentrations, resulting in markedly reduced serum cortisol concentrations. During post-marketing use, there have been reports of clinically significant interactions in patients receiving FLIXONASE AQUEOUS NASAL SPRAY and ritonavir, resulting in systemic corticosteroid effects including Cushing's syndrome and adrenal suppression. Therefore, concomitant use of FLIXONASE AQUEOUS NASAL SPRAY and ritonavir should be avoided, unless the potential benefit to the patient outweighs the risk of systemic corticosteroid side effects.

Studies have shown that other inhibitors of cytochrome P450 3A4 produce negligible (erythromycin) and minor (ketoconazole) increases in systemic exposure to fluticasone

propionate without notable reductions in serum cortisol concentrations. Nevertheless, care is advised when co-administering potent cytochrome P450 3A4 inhibitors (e.g. ketoconazole), as there is potential for increased systemic exposure to fluticasone propionate.

4.6 Fertility, pregnancy and lactation

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

4.7 Ability to drive and use machines

FLIXONASE AQUEOUS NASAL SPRAY is unlikely to produce an effect.

4.8 Undesirable effects

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 and not known (cannot be estimated from the available data).

Clinical trial data

Nervous system disorders:

Common: headache, unpleasant taste, unpleasant smell.

As with other nasal sprays, unpleasant taste and smell and headache have been reported.

Respiratory, thoracic and mediastinal disorders:

Very common: epistaxis.

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

Post-marketing data:

Immune system disorders:

Very rare: hypersensitivity reactions including skin rash, oedema of the face or tongue; anaphylaxis/anaphylactic reactions; bronchospasm.

Eye disorders:

Very rare: glaucoma, raised intraocular pressure, cataract

Respiratory, thoracic and mediastinal disorders:

Very rare: nasal septal perforation

Not known: nasal ulcers.

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of FLIXONASE AQUEOUS NASAL SPRAY is important. It allows continued monitoring of the benefit/risk balance of FLIXONASE AQUEOUS NASAL SPRAY. Health care providers are asked to report any suspected adverse reactions to: SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose

See section 4.8.

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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 21.5.1 Corticosteroids and analogues.

Pharmacotherapeutic group: Decongestants and other nasal preparations for topical use. Corticosteroids.

ATC code: R01AD08.

Fluticasone propionate has anti-inflammatory activity.

5.2 Pharmacokinetic properties

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

5.3 Preclinical safety data

No further information of relevance available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carboxymethylcellulose sodium

Dextrose (anhydrous)

Diluted hydrochloric acid

Microcrystalline cellulose

Polysorbate 80

Purified water

Benzalkonium chloride

Phenylethyl alcohol.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Amber glass bottle presentation:

36 months.

White plastic bottle presentation:

24 months.

6.4 Special precautions for storage

Store at or below 30 °C.

Protect from light.

6.5 Nature and contents of container

FLIXONASE AQUEOUS NASAL SPRAY is supplied in an amber glass bottle or 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.

6.6 Special precautions for disposal and other handling

Shake gently before use.

7. HOLDER OF CERTIFICATE OF REGISTRATION

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

8. REGISTRATION NUMBER

X/21.5.1/359

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

27 June 1991

10. DATE OF REVISION OF THE TEXT

6 December 2020

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