FLIXOTIDE ACCUHALER

SCHEDULING STATUS:

S3

PROPRIETARY NAME AND DOSAGE FORM:

FLIXOTIDE 50 ACCUHALER

FLIXOTIDE 100 ACCUHALER

FLIXOTIDE 250 ACCUHALER

FLIXOTIDE 500 ACCUHALER

Powder for Inhalation

COMPOSITION:

FLIXOTIDE ACCUHALER is a moulded plastic device containing a foil strip with 60 regularly spaced blisters. Each blister contains a mixture of 50 µg microfine fluticasone propionate and 12,45 mg lactose, 100 µg microfine fluticasone propionate and 12,4 mg lactose, 250 µg microfine fluticasone propionate and 12,25 mg lactose or 500 µg microfine fluticasone propionate and 12,0 mg lactose. The lactose particles are larger in size.

Contains sugar (lactose).

PHARMACOLOGICAL CLASSIFICATION:

A 21.5.1 Corticosteroids and analogues

PHARMACOLOGICAL ACTION:

Pharmacodynamic properties:

Fluticasone propionate in *vitro* has a potent glucocorticoid anti-inflammatory action.

Pharmacokinetic properties:

Following oral administration 87-100 % of the dose is excreted in the faeces, up to 75 % as parent compound depending on the dose. There is a non-active major metabolite.

Following intravenous administration there is rapid plasma clearance suggestive of extensive hepatic extraction. The plasma elimination half-life is approximately 3 hours.

The volume of distribution is approximately 250 litres.

INDICATIONS:

Prophylactic management of atopic asthma in adults and children of 6 years and older.

CONTRA-INDICATIONS:

FLIXOTIDE ACCUHALER is contra-indicated in patients with a history of allergy to any of its components.

WARNINGS AND SPECIAL PRECAUTIONS:

Treatment with FLIXOTIDE ACCUHALER should not be stopped abruptly as adrenal insufficiency may be precipitated in this way.

Systemic corticosteroid effects may occur in patients on fluticasone treatment. Patients transferred from other inhaled steroids or oral steroids remain at risk of impaired adrenal reserve for a considerable time after transferring to inhaled fluticasone propionate.

Increasing use of short-acting inhaled beta$_2$-agonists to control symptoms indicates deterioration of asthma control. Under these conditions, the patient should be reassessed. Sudden and progressive deterioration in asthma control is potentially life-threatening and may have several causes. Consideration should be given to increasing corticosteroid dosage if not caused by otherwise treatable causes of deterioration.

Severe asthma requires regular medical assessment as death may occur.

Patients with severe asthma may require high dose inhaled (see dosage instructions) or oral corticosteroid therapy. Sudden worsening of symptoms may require increased corticosteroid dosage which should be administered under urgent medical supervision.

Patients weaned off oral steroids whose adrenocortical function is still impaired should carry a steroid warning card indicating that they may need supplementary systemic steroid during periods of stress, e.g. worsening asthma attacks, chest infections, major intercurrent illness, surgery, trauma, etc.

In rare cases inhaled therapy may unmask underlying eosinophilic conditions (e.g. Churg Strauss syndrome). These cases have usually been associated with reduction or withdrawal of oral corticosteroid therapy. A direct causal relationship has not been established.

Similarly replacement of systemic steroid treatment with inhaled therapy may unmask allergies such as allergic rhinitis or eczema previously controlled by the systemic drug. These allergies should be symptomatically treated with antihistamine and/or topical preparations, including topical steroids.

Patients in a medical or surgical emergency, who require high doses of inhaled steroids and/or intermittent treatment with oral steroids, are at risk of impaired adrenal reserve.

The extent of the adrenal impairment may require specialist advice before elective procedures. The possibility of residual impaired adrenal response should always be borne in mind in emergency and elective situations likely to produce stress and appropriate corticosteroid treatment must be considered.

In children taking recommended doses of inhaled fluticasone propionate adrenal function and adrenal reserve usually remain within the normal range. However, the possible effects of previous or intermittent treatment with oral steroids should not be discounted.

Lack of response or severe exacerbations of asthma should be treated by increasing the dose of inhaled fluticasone propionate or by giving a systemic steroid and/or an antibiotic if there is an infection.

Special care is necessary in patients with active or quiescent pulmonary tuberculosis.

Patients on corticosteroid therapy may have adrenocortical suppression.

Effects on ability to drive and use machines:

FLIXOTIDE ACCUHALER is unlikely to produce an effect.

Excipient warnings:

Contains fructose/lactose. Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not use FLIXOTIDE ACCUHALER. Lactose may have an effect on the glycaemic control of patients with diabetes mellitus.

INTERACTIONS:

No specific interaction studies have been performed.

PREGNANCY AND LACTATION:

Safety during pregnancy and lactation has not been established.

Corticosteroids have been shown to be teratogenic in animals. As these agents are absorbed when inhaled, teratogenicity following inhalation cannot be excluded.

DOSAGE AND DIRECTIONS FOR USE:

FLIXOTIDE ACCUHALER is for inhalation use only.

Patients should be made aware of the prophylactic nature of therapy with inhaled fluticasone propionate and that it should be taken regularly even when they are asymptomatic. The onset of therapeutic effect is 4 to 7 days.

FLIXOTIDE ACCUHALER is not for relief in acute attacks but for routine long-term management.

Patients will require a fast- and short-acting inhaled bronchodilator to relieve acute asthmatic symptoms.

The dosage of FLIXOTIDE ACCUHALER should be adjusted according to the individual response.

If patients find that relief with short-acting bronchodilator treatment becomes less effective or they need more inhalations than usual, medical attention must be sought.

Adults and children over 16 years of age:

100 to 1 000 µg twice daily.

Patients should be given a starting dose of inhaled fluticasone propionate which is appropriate for the severity of their disease. The dose may be adjusted until control is achieved or reduced to the mimimum effective dose, according to the individual response.

Children over 6 years of age:

50 to 100 µg twice daily.

The dose may be adjusted until control is achieved and should be reduced to the minimum effective dose according to the individual response.

Special patient groups:

There is no need to adjust the dose in elderly patients.

For the transfer of patients being treated with oral corticosteroids:

- Patients who have been treated with systemic steroids for long periods of time or at a high dose may have adrenocortical suppression. With these patients adrenocortical function should be monitored regularly and their dose of systemic steroid reduced cautiously.
- After approximately a week, gradual withdrawal of the systemic steroid may be commenced. Decrements in dosages should be appropriate to the level of maintenance systemic steroid, and

introduced at not less than weekly intervals. For maintenance doses of prednisolone (or equivalent) of 10 mg daily or less, the decrements in dose should not be greater than 1 mg per day, at not less than weekly intervals. For maintenance doses of prednisolone in excess of 10 mg daily, it may be appropriate to employ cautiously, larger decrements in dose at weekly intervals. In some patients on oral corticosteroids the dose reduction or replacement with inhaled corticosteroids may not be possible.

- Some patients feel unwell in a non-specific way during the withdrawal phase despite maintenance or even improvement of the respiratory function. They should be encouraged to persevere with inhaled fluticasone propionate and to continue withdrawal of systemic steroid, unless there are objective signs of adrenal insufficiency.

SIDE EFFECTS:

Candidiasis of the mouth and throat (thrush) may occur. Such patients may find it helpful to rinse out their mouth with water after using the ACCUHALER. Symptomatic candidiasis can be treated with topical anti-fungal therapy whilst still continuing with the FLIXOTIDE ACCUHALER.

Inhaled fluticasone propionate may cause hoarseness. It may be helpful to rinse out the mouth with water immediately after inhalation.

Paradoxical bronchospasm may occur with an immediate increase in wheezing after dosing. This should be treated immediately with a fast-acting inhaled bronchodilator. FLIXOTIDE ACCUHALER should be discontinued immediately, the patient assessed, and if necessary alternative therapy instituted.

Cutaneous hypersensitivity reactions have been reported.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Acute - Inhalation of the drug at dosages in excess of those recommended may lead to temporary suppression of adrenal function. This does not necessitate emergency action being taken. In these

patients treatment with fluticasone propionate by inhalation should be continued at a dose sufficient to control asthma; adrenal function recovers in a few days and can be verified by measuring plasma cortisol.

Chronic - Use of inhaled fluticasone propionate in daily doses in excess of 2 mg over prolonged periods may lead to some degree of adrenal suppression. Monitoring of adrenal reserve may be indicated. Treatment with inhaled fluticasone propionate should be continued at a dose sufficient to control asthma.

IDENTIFICATION:

FLIXOTIDE 50, 100, 250 and 500 ACCUHALERS are circular devices in moulded plastic, containing foil strips with 60 regularly spaced blisters. Each blister contains a white powder.

PRESENTATION:

FLIXOTIDE ACCUHALER is a circular device in moulded plastic, containing a foil strip with 60 regularly spaced blisters. Each blister contains a mixture of microfine fluticasone propionate (50 µg, 100 µg, 250 µg or 500 µg) and larger particle size lactose. The device contains a dose counter which shows the number of doses remaining (60 to 1). To show when the last five doses have been reached, the number appears in red.

The FLIXOTIDE ACCUHALER is packaged into a foil laminate overwrap.

STORAGE INSTRUCTIONS:

Store in a dry place at or below 30 ºC.

Keep out of reach of children.

REGISTRATION NUMBER:

FLIXOTIDE 50 ACCUHALER: 30/21.5.1/0068

FLIXOTIDE 100 ACCUHALER: 30/21.5.1/0069

FLIXOTIDE 250 ACCUHALER: 30/21.5.1/0070

FLIXOTIDE 500 ACCUHALER: 30/21.5.1/0071

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

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MANUFACTURER:

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Evreux, France

Botswana:

Flixotide 50 Accuhaler - Reg No BOT1702949 S2

Flixotide 100 Accuhaler - Reg No BOT1702951 S2

Flixotide 250 Accuhaler - Reg No BOT1702952 S2

Flixotide 500 Accuhaler - Reg No BOT1702953 S2

Malawi:

Flixotide 100, 250 and 500 Accuhaler – Reg No PMPB/PL272/192 POM

Namibia:

Flixotide 50 Accuhaler - Reg No 04/21.5.1/0877 NS2

Flixotide 100 Accuhaler - Reg No 04/21.5.1/0876 NS2

Flixotide 250 Accuhaler - Reg No 04/21.5.1/0875 NS2

Flixotide 500 Accuhaler - Reg No 04/21.5.1/0874 NS2

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