FOXAIR® INHALER

SCHEDULING STATUS:

S4

PROPRIETARY NAME AND DOSAGE FORM:

FOXAIR® 25/50 INHALER

FOXAIR® 25/125 INHALER

FOXAIR® 25/250 INHALER

Metered-dose inhaler

COMPOSITION:

Each single actuation of FOXAIR provides:

Salmeterol xinafoate equivalent to 25 μg of salmeterol and 50, 125 or 250 μg of fluticasone propionate.

Excipient: Hydrofluoralkane 134a propellant (HFA 134a).

PHARMACOLOGICAL CLASSIFICATION:

A 21.5.1 Corticosteroids and analogues

PHARMACOLOGICAL ACTION:

Pharmacodynamic properties:

FOXAIR contains salmeterol and fluticasone propionate which have differing modes of action.

Salmeterol is a selective beta$_2$-adrenoceptor agonist. Salmeterol has been shown to produce long-lasting bronchodilatation of at least 12 hours in subjects with reversible

airways obstruction. *In vitro* tests have shown salmeterol to be a potent and long-lasting inhibitor of the release, from human lung, of mast cell derived mediators, such as histamine, leukotrienes and prostaglandin D_2. In man salmeterol inhibits the early and late phase response to inhaled allergen and after single dosing attenuates bronchial hyperresponsiveness.

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:

FOXAIR INHALER is indicated in the regular prophylactic treatment of atopic asthma in children and adults, who have been stabilised on identical dosages of the components of FOXAIR given concurrently.

CONTRA-INDICATIONS:

FOXAIR INHALER is contra-indicated in patients with a history of hypersensitivity to any of the ingredients.

WARNINGS AND SPECIAL PRECAUTIONS:

FOXAIR is not for relief of acute symptoms for which a fast and short-acting bronchodilator is required. Patients should be advised to have their relief medication available at all times.

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.

Patients on corticosteroid therapy may have adrenocortical suppression.

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

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

FOXAIR should be administered with caution in patients with thyrotoxicosis.

Systemic effects may occur with any inhaled corticosteroid, particularly at high doses prescribed for long periods; these effects are much less likely to occur than with oral corticosteroids. Possible systemic effects include adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density, cataract and glaucoma. It is important, therefore, that the dose of inhaled corticosteroid is titrated to the lowest dose at which effective control is maintained.

It is recommended that the height of children receiving prolonged treatment with inhaled corticosteroid is regularly monitored.

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.

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.

Patients with severe asthma may require high dose inhaled (see DOSAGE AND DIRECTIONS FOR USE) 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.

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.

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

Effects on ability to drive and use machines:

FOXAIR is unlikely to produce an effect.

INTERACTIONS:

Due to the very low plasma concentrations achieved after inhaled dosing clinically significant drug interactions are unlikely. Care should be taken when co-administering known strong CYP3A4 inhibitors (e.g. ketoconazole, ritonavir) as there is potential for increased systemic exposure to fluticasone propionate.

Both non-selective and selective beta-blockers should be avoided in patients with reversible obstructive airways disease, unless there are compelling reasons for their use.

PREGNANCY AND LACTATION:

Safety in pregnancy and lactation has not been established.

Fluticasone propionate:

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.

Salmeterol:

Safety in pregnancy has not been established. There is no experience of the use of salmeterol in breastfeeding mothers.

DOSAGE AND DIRECTIONS FOR USE:

FOXAIR INHALER is for oral inhalation use only.

Patients should be made aware that FOXAIR INHALER must be used regularly for optimum benefit, even when asymptomatic.

Patients should be regularly reassessed by a doctor so that the dosage of FOXAIR they are receiving remains optimal and is only changed on medical advice.

The dose should be titrated to the lowest dose at which effective control of symptoms is maintained.

FOXAIR INHALER is not for relief of acute symptoms for which a fast and short-acting bronchodilator is required. Patients should be advised to have their relief medication available at all times.

Increasing use of short-acting bronchodilators to relieve asthma symptoms indicates deterioration of asthma control.

Sudden and progressive deterioration in control of asthma is potentially life-threatening and the patient should be reviewed. Consideration should be given to increasing corticosteroid therapy. Also, where the current dosage of FOXAIR has failed to give adequate control of reversible obstructive airways disease, the patient should be reviewed. Consideration should be given to additional corticosteroid therapies, and to include administration of antibiotics if an infection is present.

Treatment with FOXAIR should not be stopped abruptly.

Recommended Doses:

Shake the inhaler well before use.

Adults and adolescents 12 years and older:

Two inhalations of FOXAIR 25/50 twice daily.

OR

Two inhalations of FOXAIR 25/125 twice daily.

OR

Two inhalations of FOXAIR 25/250 twice daily.

Special patient groups:

There is no need to adjust the dose in elderly patients or in those with renal or hepatic impairment.

SIDE 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.

As FOXAIR contains salmeterol and fluticasone propionate, the type and severity of adverse reactions associated with each of the compounds may be expected.

Adverse events which have been associated with salmeterol or fluticasone propionate are given below.

Salmeterol:

Clinical trials data:

Immune system disorders:

Hypersensitivity reactions:

Uncommon: rash

Nervous system disorders:

Common: tremor, headache

Cardiac disorders:

Common: palpitations

Musculoskeletal and connective tissue disorders:

Common: muscle cramps.

Post-marketing data:

Immune system disorders: hypersensitivity reactions: oedema and angioedema

Metabolism and nutrition disorders: hypokalaemia

Cardiac disorders: cardiac arrythmias including atrial fibrillation, supraventricular tachycardia and extrasystoles

Respiratory, thoracic and mediastinal disorders: oropharyngeal irritation

Musculoskeletal and connective tissue disorders: arthralgia.

Fluticasone propionate:

Clinical trials data:

Infections and infestations:

Very common: candidiasis of mouth and throat

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

Immune system disorders:

Hypersensitivity reactions with the following manifestations have been reported:

Uncommon: cutaneous hypersensitivity reactions

Respiratory, thoracic and mediastinal disorders:

Common: hoarseness

Hoarseness may occur. Such patients may find it helpful to gargle with water after using the INHALER.

Post-marketing data:

Endocrine disorders: possible systemic effects include (see WARNINGS AND SPECIAL PRECAUTIONS) adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density, cataract, glaucoma

Immune system disorders: angioedema (mainly facial and oropharyngeal oedema), respiratory symptoms (dyspnoea and/or bronchospasm) and anaphylactic reactions

Respiratory, thoracic and mediastinal disorders: paradoxical bronchospasm.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

The symptoms and signs of salmeterol overdosage are tremor, headache and tachycardia. The preferred antidote for overdosage with salmeterol inhaler is a cardio-selective beta-blocking agent. Both non-selective and selective beta-blockers should be avoided in patients with reversible obstructive airways disease, unless there are compelling reasons for their use.

Acute - Inhalation of fluticasone propionate 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 at doses in excess of those recommended 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:

Actuator and metal can with concave base fitted with a metering valve. The canister contains a white to off-white suspension.

PRESENTATION:

The suspension is contained in an aluminium alloy can sealed with a metering valve. The canisters are fitted into plastic actuators incorporating an atomising orifice and fitted with

dustcaps. FOXAIR INHALER has been formulated in three strengths and one pack size, delivering 120 actuations per inhaler. FOXAIR INHALER is packed in a carton.

STORAGE INSTRUCTIONS:

Store at or below 30 ºC.

Protect from frost and direct sunlight.

Keep out of reach of children.

REGISTRATION NUMBER:

FOXAIR 25/50 INHALER – 42/21.5.4/0244

FOXAIR 25/125 INHALER – 42/21.5.4/0245

FOXAIR 25/250 INHALER – 42/21.5.4/0246

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

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

DATE OF PUBLICATION OF THE PACKAGE INSERT:

26 November 2010

GDS-7

SKEDULERINGSTATUS:

S4

EIENDOMSNAAM EN DOSEERVORM:

FOXAIR® 25/50 INHALER (Inhaleerder)

FOXAIR® 25/125 INHALER (Inhaleerder)

FOXAIR® 25/250 INHALER (Inhaleerder)

Afgemete dosis inhaleerder

SAMESTELLING:

Elke enkele aktivering van FOXAIR verskaf:

Salmeterolxinafoaat ekwivalent aan 25 µg salmeterol en 50, 125 of 250 µg flutikasoonpropionaat.

Mengmiddel: Hidrofluooralkaan 134a dryfmiddel (HFA 134a).

FARMAKOLOGIESE KLASSIFIKASIE:

A 21.5.1 Kortikosteroïede en analoë

FARMAKOLOGIESE WERKING:

Farmakodinamiese eienskappe:

FOXAIR bevat salmeterol en flutikasoonpropionaat wat verskillende maniere van werking het.

Salmeterol is 'n selektiewe beta$_2$-adrenoseptoragonis. Daar kon aangedui word dat salmeterol langdurige brongodilatasie van ten minste 12 uur by proefpersone met omkeerbare lugwegobstruksie, kon veroorsaak. *In vitro* toetse het aangedui dat salmeterol 'n potente en langwerkende inhibeerder is van die vrystelling uit die menslike long van

massel afgeleide bemiddelaars, soos histamien, leukotriene en prostaglandien-D_2. By die mens, inhibeer salmeterol die vroeë en laat-fasereaksie op ingeasemde allergeen en na 'n enkeldosis verlaag dit brongiale hiperreaktiwiteit.

Flutikasoonpropionaat *in vitro* het 'n potente glukokortikoïede anti-inflammatoriese werking.

Farmakokinetiese eienskappe:

Na orale toediening word 87-100 % van die dosis in die feses uitgeskei, waarvan tot 75 %, afhangende van die dosis, as die stamverbinding uitgeskei word. 'n Nie-aktiewe hoofmetaboliet kom voor.

Na intraveneuse toediening vind vinnige plasmaopruiming plaas wat op ekstensiewe hepatiese ekstraksie dui. Die plasma-eliminasiehalfleeftyd is ongeveer 3 uur. Die volume van distribusie is ongeveer 250 liter.

INDIKASIES:

FOXAIR INHALER word aangedui vir die gereelde profilaktiese behandeling van atopiese asma in kinders en volwassenes wat op identiese dosisse van die komponente van FOXAIR wat gelyktydig toegedien word, gestabiliseer is.

KONTRA-INDIKASIES:

FOXAIR INHALER is teenaangedui in pasiënte met 'n geskiedenis van hipersensitiwiteit teenoor enigeen van sy komponente.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS:

FOXAIR is nie vir die verligting van akute simptome waarvoor 'n vinnige en kortwerkende brongodilator nodig is, bedoel nie. Pasiënte moet aangeraai word om hulle verligtingsmedikasie altyd beskikbaar te hê.

Toenemende gebruik van kortwerkende ingeasemde beta$_2$-agoniste om simptome te beheer, is ’n aanduiding dat asma beheer agteruitgaan. Onder hierdie toestande behoort die pasiënt weer geëvalueer te word.

Skielike en progressiewe agteruitgang in asma beheer is potensieel lewensbedreigend en mag verskeie oorsake hê.

Pasiënte op kortikosteroïedterapie mag aan adrenokortikale onderdrukking ly.Behandeling met FOXAIR behoort nie skielik gestaak te word nie omdat adrenale ontoereikendheid op hierdie manier gepresipiteer mag word.

Spesiale sorg is noodsaaklik in pasiënte met aktiewe of sluimerende pulmonale tuberkulose.

FOXAIR moet met omsigtigheid aan pasiënte met tirotoksikose toegedien word.

Sistemiese effekte mag met enige ingeasemde kortikosteroïed voorkom, veral teen hoë dosisse wat vir lang tydperke voorgeskryf word; hierdie effekte is baie minder geneig om voor te kom as met orale kortikosteroïede. Moontlike sistemiese effekte sluit in adrenale onderdrukking, groeivertraging in kinders en adolessente, vermindering in beenmineraaldensiteit, katarak en gloukoom. Dit is dus belangrik dat die dosis ingeasemde kortikosteroïed getitreer word tot die laagste dosis waarteen effektiewe beheer onderhou kan word.

Dit word aanbeveel dat die lengte van kinders wat langdurige behandeling met ingeasemde kortikosteroïed ontvang, gereeld gemoniteer word.

Sistemiese effekte van kortikosteroïede mag in pasiënte op flutikasoonterapie voorkom. Pasiënte wat van ander ingeasemde steroïede of orale steroïede oorgeskakel word, is steeds aan die risiko van ingekorte adrenale reserwe vir ’n aansienlike tyd na oorskakeling na ingeasemde flutikasoonproprionaat blootgestel.

Pasiënte in ’n mediese of chirurgiese noodtoestand, wat hoë dosisse ingeasemde steroïede en/of wisselende behandeling met orale steroïede benodig, is aan die risiko van ingekorte adrenale reserwe blootgestel.

Die advies van ’n spesialis mag voor elektiewe prosedures benodig word afhangende van die mate van adrenale inkorting. Die moontlikheid van residuele ingekorte adrenale reaksie behoort altyd in gedagte gehou te word in nood- en elektiewe situasies wat geneig is om stres te veroorsaak en toepaslike kortikosteroïedbehandeling moet oorweeg word.

By kinders wat aanbevole dosisse van ingeasemde flutikasoonpropionaat neem, bly adrenale funksie en adrenale reserwe gewoonlik binne die normale reikwydte. Die moontlik effekte van vorige of wisselende behandeling met orale steroïede moet nie buite rekening gelaat word nie.

Pasiënte met ernstige asma mag hoë-dosis ingeasemde (sien DOSIS EN GEBRUIKSAANWYSINGS) of orale kortikosteroïedterapie, benodig.

Skielike verergering van simptome mag verhoogde kortikosteroïed-dosering benodig wat onder dringende mediese toesig toegedien moet word.

Pasiënte wat van orale steroïede gespeen word, by wie die adrenokortikale funksie steeds ingekort is, behoort ’n steroïedwaarskuwingskaart te dra dat hulle supplementêre sistemiese steroïed mag nodig hê tydens periodes van stres, bv. verergering van asma-aanvalle, borsinfeksies, ernstige herhalende siekte, chirurgie, trouma, ens.

In seldsame gevalle mag inhalasie terapie onderliggende eosinofilie-toestande (bv. Churg-Strauss-sindroom) ontmasker. Hierdie gevalle was gewoonlik geassosieer met vermindering of onttrekking van orale kortikosteroïedterapie. ’n Direkte oorsaaklike verwantskap is nie vasgestel nie.

Gebrek aan reaksie of ernstige verergerings van asma behoort behandel te word deur die dosis ingeasemde flutikasoonpropionaat te verhoog of ’n sistemiese steroïed en/of ’n antibiotikum te gee indien ’n infeksie teenwoordig is.

Paradoksale brongospasma mag voorkom met ’n onmiddellike toename in hyg na dosering. Dit behoort onmiddellik met ’n vinnig werkende ingeasemde brongodilator behandel te word. FOXAIR behoort dadelik gestaak te word, die pasiënt moet geëvalueer, en indien nodig moet alternatiewe terapie begin word.

Effekte op die vermoë om te bestuur en masjiene te gebruik:

Dit is onwaarskynlik dat FOXAIR ’n effek sal veroorsaak.

INTERAKSIES:

As gevolg van die baie lae plasmavlakke wat bereik word na ingeasemde dosering, is klinies beduidende geneesmiddelinteraksies onwaarskynlik. Sorg moet geneem word wanneer dit saam met sterk CYP 3A4-inhibeerders (bv. ketokonasool, ritonavir) toegedien word omdat daar ’n potensiaal vir verhoogde sistemiese blootstelling aan flutikasoonpropionaat bestaan.

Beide nie-selektiewe en selektiewe betablokkeerders moet vermy word in pasiënte met omkeerbare obstruktiewe lugwegsiekte, tensy daar oortuigende redes vir hul gebruik bestaan.

SWANGERSKAP EN LAKTASIE:

Veiligheid in swangerskap en laktasie is nie vasgestel nie.

Flutikasoonpropionaat:

Veiligheid in swangerskap en laktasie is nie vasgestel nie.

Daar kan aangedui word dat kortikosteroïede in diere teratogenies is. Omdat hierdie middels geabsorbeer word wanneer dit ingeasem word, kan teratogenisiteit na inaseming nie uitgesluit word nie.

Salmeterol:

Veiligheid in swangerskap is nie vasgestel nie. Daar is geen ondervinding van die gebruik van salmeterol in borsvoedende moeders beskikbaar nie.

DOSIS EN GEBRUIKSAANWYSINGS:

FOXAIR INHALER is slegs vir orale inaseming bedoel.

Pasiënte moet bewus gemaak word dat FOXAIR INHALER gereeld gebruik moet word vir optimale voordeel selfs wanneer die pasiënt asimptomaties is.

Pasiënte moet gereeld deur ’n dokter weer geëvalueer word sodat die dosis FOXAIR wat hulle ontvang optimaal bly en dit slegs met mediese advies verander word.

Die dosis moet getitreer word tot die laagste dosis waarteen effektiewe beheer van simptome onderhou word.

FOXAIR INHALER is nie vir die verligting van akute simptome bedoel nie, waarvoor ’n vinnige en kortwerkende brongodilator nodig is. Pasiënte moet aangeraai word om hulle verligtingsmedikasie altyd beskikbaar te hê.

Toenemende gebruik van kortwerkende brongodilatore om asmasimptome te verlig, is ’n aanduiding dat asma beheer agteruitgaan.

Skielike en progressiewe agteruitgang in asma beheer is potensieel lewensbedreigend en die pasiënt behoort weer geëvalueer te word. Oorweging moet geskenk word om kortikosteroïedterapie te verhoog. Die pasiënt behoort ook weer geëvalueer te word as die huidige dosis FOXAIR nie geslaag het om toereikende beheer van omkeerbare obstruktiewe lugwegsiekte te verskaf nie. Oorweging moet geskenk word aan addisionele kortikoïedterapieë, en om toediening van antibiotika in te sluit indien ’n infeksie teenwoordig is.

Behandeling met FOXAIR behoort nie skielik gestaak te word nie.

Aanbevole Dosisse:

Skud die inhaleerder goed voor gebruik.

Volwassenes en adolessente van 12 jaar en ouer:

Twee inhalasies van FOXAIR 25/50 twee keer daagliks.

OF

Twee inhalasies van FOXAIR 25/125 twee keer daagliks.

OF

Twee inhalasies van FOXAIR 25/250 twee keer daagliks.

Spesiale pasiëntgroepe:

Dit is nie nodig om die dosis in bejaarde pasiënte of dié met renale of hepatiese inkorting aan te pas nie.

NEWE-EFFEKTE:

Nadelige insidente word hierna gelys volgens sisteem-orgaanklas en frekwensie. Frekwensies word gedefinieer as: baie algemeen (≥ 1/10), algemeen (≥ 1/100 en < 1/10), ongewoon (≥ 1/1 000 en < 1/100), seldsaam (≥ 1/10 000 en < 1/1 000) en baie seldsaam (< 1/10 000), insluitend geïsoleerde berigte.

Omdat FOXAIR salmeterol en flutikasoonpropionaat bevat, kan die soort en erns van nadelige reaksies wat met elkeen van die verbindings geassosieer word, verwag word.

Die nadelige insidente wat met salmeterol en flutikasoonpropionaat geassosieer is, word hierna aangee:

Salmeterol:

Data van kliniese studies:

Immuunsisteemversteurings:

Hipersensitiwiteitsreaksies:

Ongewoon: veluitslag

Senusisteemversteurings:

Algemeen: tremor, hoofpyn

Kardiale versteurings:

Algemeen: hartkloppings

Muskuloskeletale en bindweefselversteurings:

Algemeen: spierkrampe.

Nabemarkingdata:

Immuunsisteemversteurings: hipersensitiwiteitsreaksies: edeem en angio-edeem

Metabolisme en voedingversteurings: hipokalemie

Kardiale versteurings: kardiale aritmieë insluitend atriale fibrillasie, supraventrikulêre tagikardie en ekstrasistole.

Respiratoriese, torakale en mediastinale versteurings: orofaringeale irritasie.

Muskuloskeletale en bindweefselversteurings: artralgie.

Flutikasoonpropionaat:

Data van kliniese studies:

Infeksies en infestasies:

Baie algemeen: candidiase van die mond en keel

Candidiase van die mond en keel (sproei) mag voorkom. Sulke pasiënte mag dit behulpsaam vind om met water te gorrel nadat hulle FOXAIR gebruik het. Simptomatiese candidiase kan met topikale swamwerende terapie behandel word terwyl FOXAIR INHALER steeds gebruik word.

Immuunsisteemversteurings:

Hipersensitiwiteitsreaksies met die volgende manifestasies is aangemeld:

Ongewoon: hipersensitiwiteitsreaksies van die vel

Respiratoriese, torakale en mediastinale versteurings:

Algemeen: heesheid

Heesheid mag voorkom. Sulke pasiënte mag dit behulpsaam vind om met water te gorrel nadat hulle die INHALEERDER gebruik het.

Nabemarkingdata:

Endokriene versteurings: **m**oontlike sistemiese effekte sluit in (sien WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS), adrenale onderdrukking, groeivertraging in kinders en adolessente, afname in beenmineraaldensiteit, katarak, gloukoom

Immuunsisteemversteurings: angio-edeem (hoofsaaklik van die gesig en orofaringeale edeem), respiratoriese simptome (dispnee en/of brongospasma) en anafilaktiese reaksies

Respiratoriese, torakale en mediastinale versteurings: paradoksale brongospasma.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:

Die simptome en tekens van salmeteroloordosering is tremor, hoofpyn en tagikardie. Die voorkeur teenmiddel vir oordosering met salmeterolinasemtoestel is ’n kardio-selektiewe betablokkeerder. Beide nie-selektiewe en selektiewe betablokkeerders moet vermy word in pasiënte met omkeerbare obstruktiewe lugwegsiekte, tensy daar oortuigende redes vir hul gebruik bestaan.

Akuut - Inhalasie van flutikasoonpropionaat teen dosisse wat die aanbevole dosisse oortref, mag lei tot tydelike onderdrukking van adrenale funksie. Noodaksie hoef nie geneem te word nie. By hierdie pasiënte behoort behandeling met flutikasoonpropionaat deur inaseming voortgesit te word teen ’n dosis wat voldoende is om asma te beheer;

adrenale funksie herstel binne ’n paar dae en kan deur meting van plasmakortisol bevestig word.

Chronies - Gebruik van ingeasemde flutikasoonpropionaat teen dosisse wat die aanbevole dosisse oortref vir lang tydperke, mag lei tot ’n sekere mate van adrenale onderdrukking. Monitering van adrenale reserwe mag aangedui wees. Behandeling met ingeasemde flutikasoonpropionaat behoort voortgesit te word teen ’n dosis wat voldoende is om asma te beheer.

IDENTIFIKASIE:

Aktiveerder en metaalkannetjie met ’n konkawe basis voorsien met ’n doseringsklep. Die kannetjie bevat ’n wit tot naaswit suspensie.

AANBIEDING:

Die suspensie word vervat in ’n aluminiumallooi kannetjie wat verseël is met ’n doseringsklep. Die kannetjies pas in plastiese aktiveerders wat ’n verstuifopening insluit en met stofwerende doppe voorsien is. FOXAIR INHALER is in drie sterktes en een verpakkingsgrootte, wat 120 aktiverings per inasemtoestel verskaf, geformuleer. FOXAIR INHALER word in ’n kartonhouer verpak.

BEWARINGSINSTRUKSIES:

Bewaar by of benede 30 °C.

Beskerm teen ryp en direkte sonlig.

Hou buite bereik van kinders.

REGISTRASIENOMMER:

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FOXAIR 25/125 INHALER - 42/21.5.4/0245

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