Patient Information Leaflet

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

FOXAIR 50/100 Accuhaler Powder for inhalation

FOXAIR 50/250 Accuhaler Powder for inhalation

FOXAIR 50/500 Accuhaler Powder for inhalation

Salmeterol 50 µg and fluticasone propionate 100 µg, 250 µg or 500 µg

Read all of this leaflet carefully before you start using FOXAIR Accuhaler.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- FOXAIR has been prescribed for you or your child personally and should not be shared with other people. It may harm them, even if their symptoms are the same as yours.

WHAT FOXAIR ACCUHALER CONTAINS:

Each FOXAIR Accuhaler blister contains 50 micrograms of the active ingredient salmeterol (as xinafoate). Each blister also contains 100 or 250 or 500 micrograms of the active ingredient microfine fluticasone propionate.

Contains sugar (lactose up to 12,5 mg per blister) as excipient.

WHAT FOXAIR ACCUHALER IS USED FOR:

Your doctor has chosen this medicine to suit you and your condition. FOXAIR Accuhaler is used to help with asthma in people who need prevention treatment.

BEFORE YOU USE FOXAIR ACCUHALER:

Do not use FOXAIR Accuhaler:

- if you are allergic to salmeterol xinafoate
- if you are allergic to fluticasone propionate
- if you are allergic to lactose or milk proteins.

Take special care with FOXAIR ACCUHALER:

Special care should be taken with FOXAIR:

- if you ever had thrush in your mouth
- if you are being or have ever been treated for tuberculosis (TB)
- if you are having treatment for a thyroid condition
- if you are you having treatment for high blood pressure or a heart problem

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using FOXAIR.

Important information about some of the ingredients of FOXAIR Accuhaler:

Each blister of powder contains lactose/fructose. Patients with the rare hereditary conditions of lactose/fructose or galactose malabsorption should not take FOXAIR Accuhaler. Lactose may have an effect on the control of your blood sugar if you have diabetes mellitus.

Using other medicines with FOXAIR Accuhaler:

Always tell your healthcare professional if you are taking other medicines. (This includes complementary or traditional medicines.)

You must not take FOXAIR Accuhaler if you are receiving a medicine called ritonavir, without first consulting your doctor. Make sure your doctor knows what other medicines you are taking, including those that you have bought yourself.

HOW TO USE FOXAIR ACCUHALER:

DO NOT use this medicine to treat a sudden attack of breathlessness as it will not help you. You will need a different type of medicine, which you must not confuse with FOXAIR Accuhaler. You should always have your fast-acting 'rescue' medicine available. It is very important that you use it regularly every day. Do not stop treatment even if you feel better unless told to do so by your doctor. Do not change your dose unless told to by your doctor. If you are breathless or wheezing more often than normal, tell your doctor.

The medicine in the FOXAIR Accuhaler should be inhaled into your lungs. You will be able to taste the powder on your tongue if you have used the Accuhaler correctly. If you have any difficulties or do not understand the instructions ask your doctor or pharmacist. FOXAIR Accuhaler must only be breathed in through the mouth. Take your medicine as your doctor has told you. The label on it will usually tell you how much to take and how often. If you are not sure ask your doctor or pharmacist.

The usual dose is:

Asthma:

Adults and adolescents 12 years and older, as prescribed by your doctor:

One inhalation (FOXAIR 50/100 Accuhaler) twice daily or

One inhalation (FOXAIR 50/250 Accuhaler) twice daily or

One inhalation (FOXAIR 50/500 Accuhaler) twice daily.

Children 4 years and older:

One inhalation (FOXAIR 50/100 Accuhaler) twice daily.

COPD:

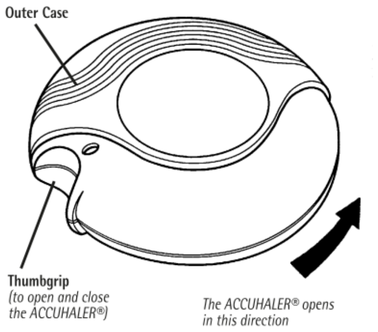
Adults: One inhalation (FOXAIR 50/250 Accuhaler) to one inhalation (FOXAIR 50/500 Accuhaler) twice daily.

Instructions for use of your FOXAIR Accuhaler:

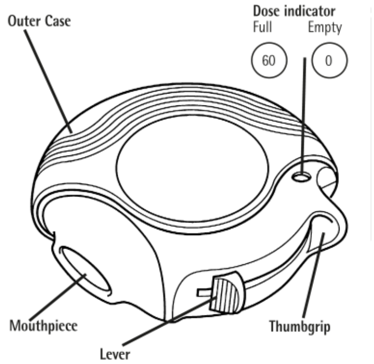
Use and Handling:

The Accuhaler releases a powder which is inhaled into the lungs. A dose indicator on the Accuhaler indicates the number of doses left.

Closed: When you take your Accuhaler out of its box, it will be in the closed position.



Opened: A new Accuhaler contains 60 doses of your medicine. The dose indicator tells you how many doses are left.



This Accuhaler contains 60 individually protected doses of your medicine, in powder form. Each dose is accurately measured and hygienically protected. It requires no maintenance - and no refilling. The dose indicator on top of your Accuhaler tells you how many doses are left.

Numbers 5 to 0 will appear in RED, to warn you when there are only a few doses left. The Accuhaler is easy to use. When you need a dose, just follow the four simple steps illustrated

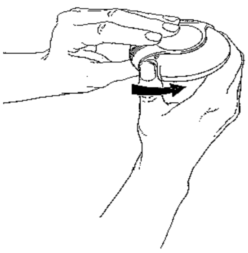
1. Open.
2. Slide.
3. Inhale.
4. Close.

How your Accuhaler works:

Sliding the lever of your Accuhaler opens a small hole in the mouthpiece and unwraps a dose, ready for you to inhale it. When you close the Accuhaler, the lever automatically moves back to its original position, ready for your next dose when you need it. The outer case protects your Accuhaler when it is not in use.

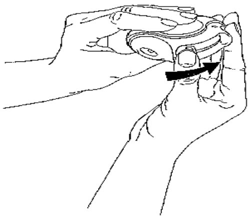
1. **Open - How to use the Accuhaler.**

   To open your Accuhaler, hold the outer case in one hand and put the thumb of your other hand on the thumbgrip. Push your thumb away from you as far as it will go.



2. **Slide.**

   Hold your Accuhaler with the mouthpiece towards you. Slide the lever away from you, as far as it will go - until it clicks. Your Accuhaler is now ready to use. Every time the lever is pushed back, a dose is made available for inhaling. This is shown by the dose counter. Do not play with the lever as this releases doses which will be wasted.



3. Inhale.

Before you start to inhale the dose, read through this section carefully.

Hold the Accuhaler away from your mouth.

Breathe out as far as is comfortable. Remember - never breathe into your Accuhaler.

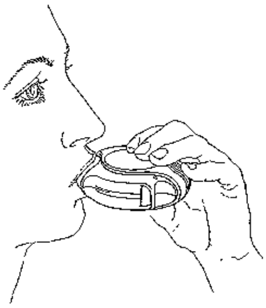
Put the mouthpiece to your lips.

Breathe in steadily and deeply - through the Accuhaler, not through your nose.

Remove the Accuhaler from your mouth.

Hold your breath for about 10 seconds, or for as long as is comfortable.

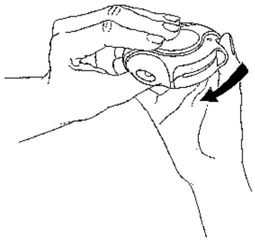
Breathe out slowly.



4. Close.

To close your Accuhaler, put your thumb in the thumbgrip, and slide the thumbgrip back towards you, as far as it will go.

When you close the Accuhaler, it clicks shut. The lever automatically returns to its original position and is reset. Your Accuhaler is now ready for you to use again.



If you have been instructed to take two inhalations you must close the Accuhaler and repeat stages 1 to 4.

Remember:

Keep your Accuhaler dry.

Keep it closed when not in use.

Never breathe into your Accuhaler.

Only slide the lever when you are ready to take a dose.

Do not exceed the stated dose. Keep out of reach of children.

After using your Accuhaler:

If your breathing or wheezing gets worse straight after using your Accuhaler or inhaler, stop using it immediately and tell your doctor as soon as possible.

If you use more FOXAIR Accuhaler than you should:

If you accidentally take a larger dose than recommended you may notice that your heart is beating faster than usual and that you feel shaky. Other symptoms you may experience include headache, muscle weakness and aching joints. Tell your doctor as soon as possible if you accidentally take a larger dose than you were told to.

If you missed a dose of FOXAIR Accuhaler:

If you miss a dose just take the next dose when it is due.

POSSIBLE SIDE EFFECTS:

FOXAIR can have side effects.

Not all side effects reported for FOXAIR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using FOXAIR, please consult your doctor, pharmacist or other healthcare professional for advise.

Some people can be allergic to medicines. If you have any of the following symptoms soon after taking FOXAIR Accuhaler, STOP taking this medicine and tell your doctor immediately.

- Sudden wheeziness and chest pain or tightness.
- Swelling of eyelids, face, lips, tongue or throat.
- Lumpy skin rash or "hives" anywhere on the body.

The above are all very serious side effects. If you have them, you may have had a serious allergic reaction to FOXAIR. You may need urgent medical attention, or hospitalisation.

Some people very occasionally find that their mouth, throat or tongue becomes sore or that their voice becomes hoarse after inhaling this medicine. Gargling with water and spitting it out immediately after each dose may help. Tell your doctor but do not stop treatment unless told to do so. Also tell your doctor if you have any of the following symptoms: headache, muscle cramps, pains in joints, skin rash or trembling, increase in pulse rate.

It is possible that some patients, particularly those taking higher doses of this type of medication, may very rarely suffer from the following side effects:

Rounded face, loss of bone density, eye problems and slowing of growth in children. If you have any other symptoms that you do not understand, tell your doctor or pharmacist.

STORING AND DISPOSING OF FOXAIR ACCUHALER:

Store in a dry place at or below 30 °C.

Store all medicines out of reach of children.

Do not use after the expiry date stated on your label or carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF FOXAIR ACCUHALER:

A single Accuhaler is packed into a carton.

FOXAIR Accuhaler is a two-tone purple, circular moulded plastic device containing a foil strip with 60 regularly spaced blisters.

The FOXAIR 50/100 Accuhaler device is labelled with pink lettering.

The FOXAIR 50/250 Accuhaler device is labelled with purple lettering.

The FOXAIR 50/500 Accuhaler device is labelled with black lettering.

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.

IDENTIFICATION OF FOXAIR ACCUHALER:

Each blister of FOXAIR 50/100, 50/250 and 50/500 Accuhaler contains a white powder.

REGISTRATION NUMBER:

FOXAIR 50/100 Accuhaler – 42/21.5.4/0581

FOXAIR 50/250 Accuhaler – 42/21.5.4/0582

FOXAIR 50/500 Accuhaler – 42/21.5.4/0583

NAME AND ADDRESS OF THE REGISTRATION HOLDER:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

DATE OF PUBLICATION:

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Date of implementation of Regulation 12: 10 December 2015

GDS-10

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Pasiëntinligtingsbrosjure

SKEDULERINGSTATUS:

S4

EIENDOMSNAAM, STERKTE EN FARMASEUTIESE VORM:

FOXAIR 50/100 Accuhaler Poeier vir inhalasie

FOXAIR 50/250 Accuhaler Poeier vir inhalasie

FOXAIR 50/500 Accuhaler Poeier vir inhalasie

Salmeterol 50 µg en flutikasoonpropionaat 100 µg, 250 µg of 500 µg

Lees hierdie hele brosjure versigtig alvorens jy begin om FOXAIR Accuhaler te gebruik.

- Bewaar hierdie brosjure. Jy mag dit weer moet lees.
- As jy enige addisionele vrae het, vra asseblief jou dokter of jou apteker.
- FOXAIR is vir jou of jou kind persoonlik voorgeskryf en jy behoort dit nie vir ander persone te gee nie. Dit kan hulle skade aandoen, al is hulle simptome dieselfde as joune.

WAT FOXAIR ACCUHALER BEVAT:

Elke FOXAIR Accuhaler stolp bevat 50 mikrogram van die aktiewe bestanddeel salmeterol (as xinafoaat). Elke stolp bevat ook 100 of 250 of 500 mikrogram van die aktiewe bestanddeel mikrofyne flutikasoonpropionaat.

Bevat suiker (tot 12,5 mg laktose per stolp) as mengmiddel.

WAARVOOR FOXAIR ACCUHALER GEBRUIK WORD:

Jou dokter het hierdie medisyne gekies om jou en jou toestand te pas. FOXAIR Accuhaler word gebruik om te help met asma by persone wat voorkomende behandeling nodig het.

VOORDAT JY FOXAIR ACCUHALER GEBRUIK:

Moenie FOXAIR Accuhaler gebruik nie:

- indien jy allergies is vir salmeterolxinafoaat
- indien jy allergies is vir flutikasoonpropionaat
- indien jy allergies is vir laktose of melkproteïene.

Neem spesiale sorg met FOXAIR ACCUHALER:

Spesiale sorg moet geneem word met FOXAIR:

- indien jy ooit sproei in jou mond gehad het
- indien jy tans vir tuberkulose (TB) behandel word of ooit daarvoor behandel is
- indien jy behandeling vir ’n tiroïedtoestand ontvang
- indien jy behandeling vir hoë bloeddruk of ’n hartprobleem ontvang.

Swangerskap en Borsvoeding:

Indien jy swanger is of jou baba borsvoed, moet jy asseblief jou dokter, apteker of ander gesondheidsorgkundige raadpleeg voordat FOXAIR vir jou gegee word.

Belangrike inligting oor sommige van die bestanddele van FOXAIR Accuhaler:

Elke stolp van poeier bevat laktose/fruktose. Pasiënte met die raar oorerflike toestande van laktose/fruktose of galaktose wanabsorpsie behoort nie FOXAIR Accuhaler te neem nie. Laktose kan ’n effek op die beheer van jou bloedsuiker hê as jy aan diabetes mellitus ly.

Gebruik van ander medisyne saam met FOXAIR Accuhaler:

Jy moet altyd jou gesondheidsorgkundige inlig indien jy tans enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)

As jy 'n medisyne ontvang wat ritonavir genoem word, moet jy nie FOXAIR Accuhaler gebruik sonder om eers jou dokter te raadpleeg nie. Maak seker dat jou dokter weet watter ander medisyne jy tans neem, insluitend dié wat jy self gekoop het.

HOE OM FOXAIR ACCUHALER TE GEBRUIK:

MOENIE hierdie medisyne neem om 'n skielike aanval van kortasem te behandel nie, omdat dit jou nie sal help nie. Jy sal 'n ander soort medisyne nodig hê, wat jy nie met FOXAIR Accuhaler moet verwar nie. Jy behoort altyd jou vinnigwerkende 'reddingsmedisyne' beskikbaar te hê. Dit is baie belangrik dat jy dit gereeld elke dag gebruik. Moenie behandeling staak nie selfs al voel jy beter, tensy jou dokter jou vertel om dit te staak. Moenie jou dosis verander nie, tensy jou dokter jou vertel om dit te doen. Indien jy meer dikwels as normaal aan kortasem of hyg ly, moet jy jou dokter daarvan vertel.

Die medisyne in die FOXAIR Accuhaler moet in jou longe ingeasem word. Jy sal die poeier op jou tong proe indien jy die Accuhaler korrek gebruik het. As jy enige probleme het of nie die instruksies verstaan nie, vra jou dokter of apteker daaroor. FOXAIR Accuhaler moet slegs deur die mond ingeasem word. Neem jou medisyne soos jou dokter aanbeveel het. Die etiket sal gewoonlik vir jou vertel hoeveel om te neem en hoe dikwels. As jy onseker is, vra jou dokter of apteker daaroor.

Die gebruiklike dosis is:

Asma:

Volwassenes en adolessente van 12 jaar en ouer, soos deur jou dokter voorgeskryf:

Een inhalasie (FOXAIR 50/100 Accuhaler) twee keer daagliks of

Een inhalasie (FOXAIR 50/250 Accuhaler) twee keer daagliks of

Een inhalasie (FOXAIR 50/500 Accuhaler) twee keer daagliks.

Kinders van 4 jaar en ouer:

Een inhalasie (FOXAIR 50/100 Accuhaler) twee keer daagliks.

COLS:

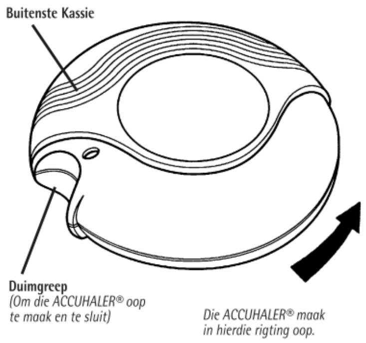
Volwassenes: Een inhalasie (FOXAIR 50/250 Accuhaler) tot een inhalasie (FOXAIR 50/500 Accuhaler) twee keer daagliks.

Instruksies vir die gebruik van jou FOXAIR Accuhaler:

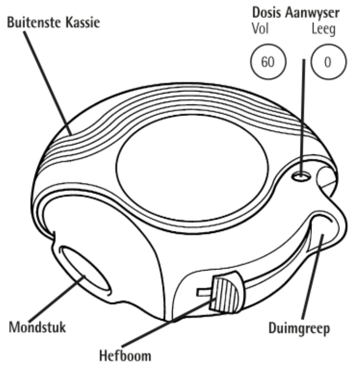
Gebruik en Hantering:

Die Accuhaler stel 'n poeier vry wat tot in jou longe ingeasem word. 'n Dosisindikator op die Accuhaler dui aan hoeveel dosisse nog oorbly.

Gesluit: Wanneer jy jou Accuhaler uit sy houer neem, sal dit in die geslote posisie wees.



Oop: 'n Nuwe Accuhaler bevat 60 dosisse van jou medisyne. Die dosisindikator dui aan hoeveel dosisse oorbly.



Hierdie Accuhaler bevat 60 individueel beskermde dosisse van jou medisyne, in poeier vorm. Elke dosis is akkuraat afgemeet en higiënies beskerm. Dit het geen onderhoud nodig nie - en hoef nie weer opgevul te word nie. Die dosisindikator bo op jou Accuhaler dui aan hoeveel dosisse nog oorbly. Die getalle 5 tot 0 sal in ROOI verskyn om jou te waarsku dat daar slegs nog ŉ paar dosisse oor is. Die Accuhaler is maklik om te gebruik. Wanneer jy ŉ dosis nodig het, volg net die vier eenvoudige stappe wat geïllustreer word.

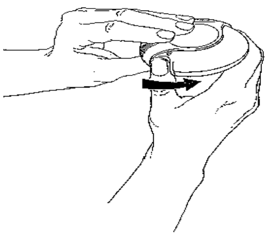
1. Maak oop.
2. Skuif.
3. Inhaleer.
4. Sluit.

Hoe jou Accuhaler werk:

As jy die hefboom van jou Accuhaler skuif, maak dit ŉ klein gaatjie in die mondstuk oop en stel die dosis bloot, gereed sodat jy dit kan inhaleer. As jy die Accuhaler toemaak, beweeg die hefboom outomaties terug na sy oorspronklike posisie, gereed vir jou volgende dosis wanneer jy dit nodig het. Die buitenste kassie beskerm jou Accuhaler wanneer dit nie in gebruik is nie.

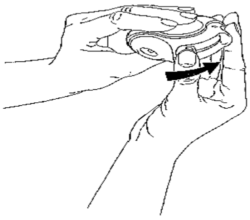
1. Maak oop - Hoe om die Accuhaler te gebruik.

Om jou Accuhaler oop te maak, hou die buitenste kassie in een hand en sit die duim van jou ander hand op die duimgreep. Druk jou duim weg van jou so ver soos wat dit sal beweeg.



2. Skuif.

Hou jou Accuhaler vas sodat die mondstuk na jou toe wys. Skuif die hefboom weg van jou so ver soos wat dit sal beweeg - totdat ʼn klikgeluid gehoor word. Jou Accuhaler is nou gereed om gebruik te word. Elke keer as die hefboom teruggestoot word, word ʼn dosis vir inhalering gereed gemaak. Dit word deur die dosisteller aangedui. Moenie met die hefboom speel nie omdat dit dosisse vrystel wat verspil sal word.



3. Inhaleer.

Voordat jy begin om die dosis te inhaleer, lees eers hierdie afdeling versigtig.

Hou die Accuhaler weg van jou mond.

Asem uit so ver soos wat gemaklik is. Onthou - moet nooit in jou Accuhaler uitasem nie.

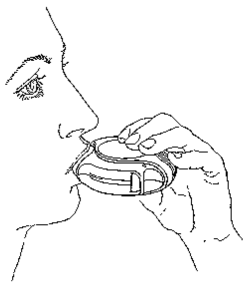
Sit die mondstuk aan jou lippe.

Asem bestendig en diep in - deur die Accuhaler, nie deur jou neus nie.

Verwyder die Accuhaler van jou mond.

Hou jou asem in vir ongeveer 10 sekondes, of vir so lank as wat gemaklik is.

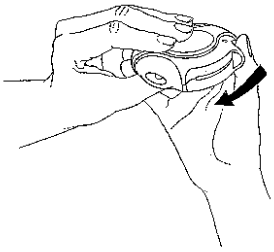
Asem stadig uit.



4. Sluit.

Om jou Accuhaler te sluit, sit jou duim op die duimgreep, en skuif die duimgreep terug na jou toe, so ver soos wat dit sal beweeg.

Wanneer jy die Accuhaler sluit, maak dit ʼn klikgeluid. Die hefboom keer outomaties terug na sy oorspronklike posisie en word weer gestel. Jou Accuhaler is nou gereed om weer deur jou gebruik te word.



As jy instruksies ontvang het dat jy twee inhalasies moet neem, moet jy die Accuhaler sluit en stappe 1 tot 4 herhaal.

Onthou:

Sorg dat jou Accuhaler droog bly.

Hou dit gesluit wanneer dit nie in gebruik is nie.

Moet nooit in jou Accuhaler uitasem nie.

Skuif alleenlik die hefboom as jy gereed is om ʼn dosis te neem.

Moenie die aanbevole dosis oorskry nie. Hou buite bereik van kinders.

Nadat jy jou Accuhaler gebruik het:

Indien jou asemhaling of hyg vererger onmiddellik nadat jy jou Accuhaler of inhaleerder gebruik het, moet jy dadelik stop om dit te gebruik en jou dokter so gou as moontlik daarvan vertel.

Indien jy meer FOXAIR Accuhaler neem, as nodig:

As jy per abuis ʼn groter dosis neem as wat aanbeveel word, mag jy agterkom dat jou hart vinniger as gewoonlik klop en dat jy bewerig voel. Ander simptome wat jy mag ondervind, sluit

hoofpyn, spierswakheid en seer gewrigte in. Vertel jou dokter so gou as moontlik daarvan as jy per abuis ŉ groter dosis neem as wat aanbeveel is.

Indien jy ’n dosis van FOXAIR Accuhaler oorgeslaan het:

As jy ŉ dosis oorslaan, neem die volgende dosis op die aangewese tyd.

MOONTLIKE NEWE-EFFEKTE:

FOXAIR kan newe-effekte veroorsaak.

Nie al die newe-effekte wat vir FOXAIR aangemeld is, word in hierdie brosjure ingesluit nie.

Indien jou algemene gesondheid vererger, of indien jy enige negatiewe effekte ondervind terwyl FOXAIR gebruik word, moet jy asseblief jou dokter, apteker of ander gesondheidsorgkundige raadpleeg vir advies.

Sommige persone kan vir medisyne allergies wees. Indien jy enigeen van die volgende simptome kort na inname van FOXAIR Accuhaler ontwikkel, moet jy hierdie medisyne STAAK en jou dokter onmiddellik daarvan vertel.

- Skielike hyg en borspyn of benoude bors.
- Swelling van die ooglede, gesig, lippe, tong of keel.
- ŉ Bulterige veluitslag of “galbulte” op enige deel van die liggaam.

Bogenoemde is almal baie ernstige newe-effekte. Indien jy hulle ondervind, mag jy ’n ernstige allergiese reaksie teenoor FOXAIR gehad het. Jy mag dalk dringende mediese behandeling of hospitalisasie benodig.

In seldsame gevalle vind sommige persone dat hul mond, keel of tong seer word of dat hul stem hees word nadat hulle hierdie medisyne inhaleer. Gorrel met water en uitspoeg daarvan onmiddellik na elke dosis mag help. Vertel jou dokter maar moenie behandeling stop nie, tensy die dokter dit aanbeveel. Vertel ook jou dokter as jy enigeen van die volgende simptome

ondervind: hoofpyn, spierkrampe, pyn in die gewrigte, veluitslag of bewerasies, ŉ verhoogde polsslag.

Dit is moontlik dat sommige pasiënte, veral dié wat hoër dosisse van hierdie soort medikasie neem, in baie seldsame gevalle aan die volgende newe-effekte mag ly:

Geronde gesig, verlies aan beendigtheid, oogprobleme en vertraging van groei by kinders.

Indien jy enige ander simptome ondervind wat jy nie verstaan nie, vertel jou dokter of apteker daarvan.

BERGING EN WEGDOENING VAN FOXAIR ACCUHALER:

Bewaar in ŉ droë plek by of benede 30 °C.

Bewaar alle medisyne buite bereik van kinders.

Moenie na die vervaldatum op jou etiket of kartonhouer, gebruik nie.

Gee alle ongebruikte medisyne terug aan jou apteker.

Moenie van ongebruikte medisyne ontslae raak in afvoerpype of rioolsisteme (bv. toilette) nie.

AANBIEDING VAN FOXAIR ACCUHALER:

’n Enkele Accuhaler is verpak in ’n kartonhouer.

FOXAIR Accuhaler is ’n ringvormige gevormde plastiese toestel wat twee skakerings van pers is, en wat ŉ foeliestrook met 60 gereeld gespasieerde stolpe bevat.

Die FOXAIR 50/100 Accuhaler toestel is met pienk letters geëtiketteer.

Die FOXAIR 50/250 Accuhaler toestel is met pers letters geëtiketteer.

Die FOXAIR 50/500 Accuhaler toestel is met swart letters geëtiketteer.

Die toestel bevat ŉ dosisteller wat die getal dosisse wat oorbly (60 tot 1) aandui.

Om aan te dui wanneer die laaste vyf dosisse bereik word, verskyn die nommer in rooi.

IDENTIFIKASIE VAN FOXAIR ACCUHALER:

Elke stolp van FOXAIR 50/100, 50/250 en 50/500 Accuhaler bevat 'n wit poeier.

REGISTRASIENOMMER:

FOXAIR 50/100 Accuhaler: 42/21.5.4/0581

FOXAIR 50/250 Accuhaler: 42/21.5.4/0582

FOXAIR 50/500 Accuhaler: 42/21.5.4/0583

NAAM EN ADRES VAN REGISTRASIEHOUER:

GlaxoSmithKline South Africa (Edms) Bpk

Hawkinslaan 39

Epping Industrie 1, 7460

DATUM VAN PUBLIKASIE:

Datum van registrasie: 4 Junie 2010

Datum van implementering van Regulasie 12: 10 Desember 2015

Handelsmerke is in besit van of gelisensieer aan die GSK-groep van maatskappye.

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