Patient Information Leaflet

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

FOXAIR 25/50 INHALER

FOXAIR 25/125 INHALER

FOXAIR 25/250 INHALER

Metered-dose inhaler

Salmeterol 25 µg and fluticasone propionate 50 µg, 125 µg or 250 µg

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

- 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 INHALER CONTAINS:

The active substances are salmeterol and fluticasone propionate.

Each single actuation of FOXAIR INHALER provides:

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

The other ingredient is CFC-free propellant, HFA 134a.

WHAT FOXAIR INHALER IS USED FOR:

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

BEFORE YOU USE FOXAIR INHALER:

Do not use FOXAIR:

- if you are hypersensitive (allergic) to salmeterol xinafoate or fluticasone propionate or the other ingredient of FOXAIR.

Take special care with FOXAIR INHALER:

- if you have 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 having treatment for high blood pressure or a heart problem

If any of these points apply to you, consult your doctor first before taking FOXAIR INHALER.

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

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.

Driving and using machinery:

FOXAIR INHALER is unlikely to produce an effect.

Using other medicines with FOXAIR INHALER:

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

In some cases, FOXAIR INHALER may not be suitable to use with other medicines (e.g. some HIV or oral anti-fungal medicines). **You must not use FOXAIR INHALER if you are receiving a medicine called ritonavir, without first consulting your doctor.**

HOW TO USE FOXAIR INHALER:

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 INHALER.

You should always have your fast-acting 'rescue' medicine available. It is very important that you use FOXAIR INHALER 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 INHALER should be inhaled into your lungs. FOXAIR INHALER must only be breathed in through the mouth. If you have any difficulties or do not understand the instructions ask your doctor or pharmacist.

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.

Shake the inhaler well before use.

The usual dose is:

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

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.

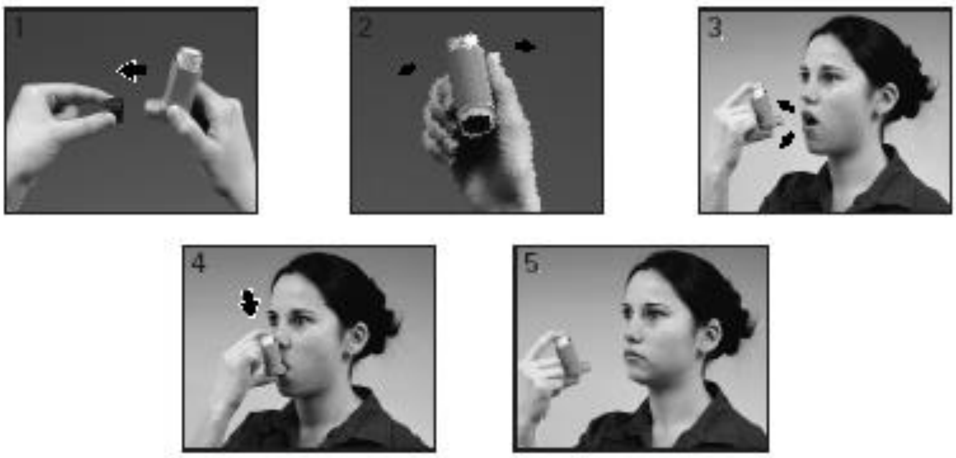
Instructions for use:

Testing your inhaler:

Before using for the first time, remove the mouthpiece cover by gently squeezing the sides of the cover, shake the inhaler well, and release one puff into the air to make sure that it works.

If your inhaler has not been used for a week or more remove the mouthpiece cover, shake the inhaler well and release one puff into the air.

Using your inhaler:



1. Remove the mouthpiece cover by gently squeezing the sides of the cover and check the mouthpiece inside and outside to see that it is clean.
2. Shake the inhaler well.
3. Hold the inhaler upright between finger/s and thumb with your thumb on the base, below the mouthpiece. Breathe out as far as is comfortable and then …

4. Place the mouthpiece in your mouth between your teeth and close your lips around it, but do not bite it. Just after starting to breathe in through your mouth press down on the top of the inhaler to release FOXAIR, while still breathing in steadily and deeply.
5. While holding your breath, take the inhaler from your mouth and take your finger from the top of the inhaler. Continue holding your breath for as long as is comfortable.
6. To take the second puff keep the inhaler upright and wait about half a minute before repeating steps 2 to 5.

The mouthpiece cover is replaced by firmly pushing and snapping the cap into position.

Important:

Do not rush stages 4 and 5. It is important that you start to breathe in as slowly as possible just before operating your inhaler. Practise in front of a mirror for the first few times. If you see "mist" coming from the top of your inhaler or the sides of your mouth you should start again from step 2.

If your doctor has given you different instructions for using your inhaler, please follow them carefully. Tell your doctor if you have any difficulties.

Cleaning:

Your inhaler should be cleaned at least once a week.

1. Remove the mouthpiece cover.
2. Do not remove the canister from the plastic casing.
3. Wipe the inside and outside of the mouthpiece and the plastic casing with a dry cloth, tissue or cottonbud.
4. Replace the mouthpiece cover.

Do not put the metal canister into water.

After using your inhaler:

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

If you use more FOXAIR INHALER 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 forget to take FOXAIR INHALER:

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

POSSIBLE SIDE EFFECTS:

FOXAIR INHALER can have side effects.

Some people can be allergic to medicines. If you have any of the following symptoms soon after taking FOXAIR INHALER, **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.

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.

Not all side effects reported for this medicine are recorded in this leaflet, Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

STORING AND DISPOSING OF FOXAIR INHALER:

Straight after use, replace the mouthpiece cover firmly and click it into position. Do not use excessive force.

Keep your inhaler away from heat or direct sunlight.

Also keep your inhaler away from frost, which may make your medicine work less well.

The can should not be punctured, broken or burnt even when it is empty. Take it to your nearest pharmacy for disposal.

Do not use after the expiry date shown as 'Exp' on the carton and label.

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

Store all medicines out of sight of children.

Return all unused medicine to your pharmacist.

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

PRESENTATION OF FOXAIR INHALER:

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.

IDENTIFICATION:

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

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 ADDRESS OF REGISTRATION HOLDER:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

DATE OF PUBLICATION:

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GDS-7

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Pasiëntinligtingsbrosjure

SKEDULERINGSTATUS:

S4

EIENDOMSNAAM, STERKTE EN FARMASEUTIESE VORM:

FOXAIR® 25/50 INHALER (Inhaleerder)

FOXAIR® 25/125 INHALER (Inhaleerder)

FOXAIR® 25/250 INHALER (Inhaleerder)

Afgemete dosis inhaleerder

Salmeterol 25 µg en flutikasoonpropionaat 50 µg, 125 µg of 250 µg

Lees hierdie hele brosjure versigtig alvorens jy begin om FOXAIR INHALER 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 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.
- FOXAIR is vir jou of jou kind persoonlik voorgeskryf, en dit behoort nie met ander persone gedeel te word nie. Dit kan hulle skade aandoen, al is hulle simptome dieselfde as joune.

WAT FOXAIR INHALER BEVAT:

Die aktiewe bestanddele is salmeterol en flutikasoonpropionaat.

Elke enkele aktivering van FOXAIR INHALER verskaf:

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

Die ander bestanddeel is CFC-vrye dryfmiddel, HFA 134a.

WAARVOOR FOXAIR INHALER GEBRUIK WORD:

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

VOORDAT JY FOXAIR INHALER GEBRUIK:

Moenie FOXAIR gebruik nie:

- indien jy vir salmeterolxinafoaat of flutikasoonpropionaat of die ander bestanddeel van FOXAIR hipersensitief (allergies) is.

Neem spesiale sorg met FOXAIR INHALER:

- 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 ʼn tiroïedtoestand ontvang
- indien jy behandeling vir hoë bloeddruk of ʼn hartprobleem ontvang.

Indien enigeen van hierdie punte op jou van toepassing is, moet jy eers jou dokter raadpleeg voordat jy FOXAIR INHALER gebruik.

Indien jou asemhaling of hyg vererger net nadat jy jou inhaleerder gebruik het, moet jy die gebruik daarvan onmiddellik staak en jou dokter so gou as moontlik daarvan vertel.

Swangerskap en Borsvoeding:

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

Bestuur en gebruik van masjiene:

Dit is onwaarskynlik dat FOXAIR INHALER ʼn effek sal veroorsaak.

Gebruik van ander medisyne saam met FOXAIR INHALER:

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

In sommige gevalle mag FOXAIR INHALER nie vir gebruik saam met ander medisyne (bv. sommige MIV of orale swamwerende medisyne), geskik wees nie. **As jy ʼn medisyne ontvang wat ritonavir genoem word, moet jy nie FOXAIR INHALER gebruik sonder om eers jou dokter te raadpleeg nie.**

HOE OM FOXAIR INHALER TE GEBRUIK:

MOENIE hierdie medisyne neem om ʼn skielike aanval van kortasem te behandel, omdat dit jou nie sal help nie. Jy sal ʼn ander soort medisyne nodig hê, wat jy nie met FOXAIR INHALER mag verwar nie.

Jy behoort altyd jou vinnigwerkende 'reddingsmedisyne' beskikbaar te hê. Dit is baie belangrik dat jy FOXAIR INHALER gereeld elke dag gebruik.

Moenie behandeling staak 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 INHALER moet in jou longe ingeasem word. FOXAIR INHALER moet alleenlik deur die mond ingeasem word. As jy enige probleme het of nie die instruksies verstaan nie, vra jou dokter of apteker daaroor.

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.

Skud die inhaleerder goed voor gebruik.

Die gebruiklike dosis is:

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

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.

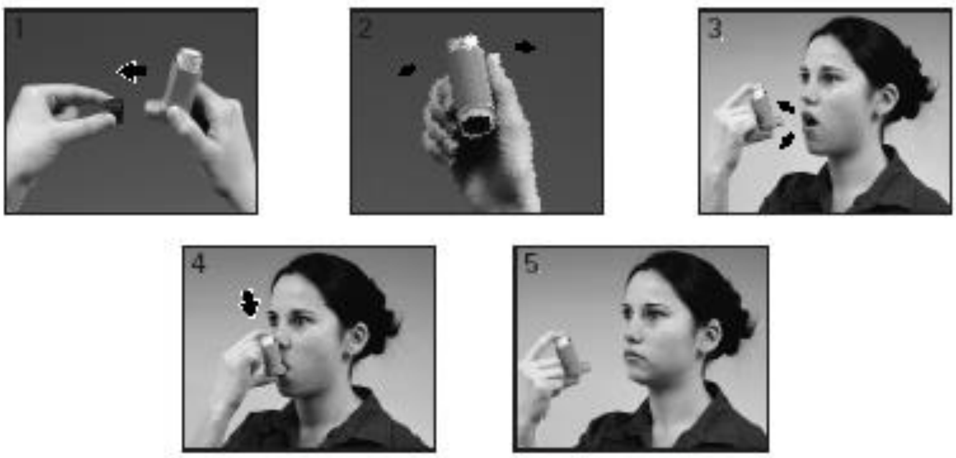
Instruksies vir gebruik:

Hoe om jou inhaleerder te toets:

Voordat jy dit vir die eerste keer gebruik, moet jy die dop van die mondstuk verwyder deur die kante van die dop versigtig te druk, die inhaleerder goed te skud, en een sproei in die lug vry te stel om seker te maak dat dit werk.

Indien jou inhaleerder vir 'n week of langer nie gebruik is nie, verwyder die dop van die mondstuk, skud die inhaleerder goed, en laat een sproei in die lug vry.

Gebruik van jou inhaleerder:



1. Verwyder die dop van die mondstuk deur die kante van die dop versigtig te druk en vas te stel of die mondstuk binne en buite skoon is.
2. Skud die inhaleerder goed.
3. Hou die inasemtoestel regop tussen jou vinger(s) en duim met jou duim op die basis, onder die mondstuk. Asem uit so ver soos wat gemaklik is en dan...
4. Plaas die mondstuk in jou mond tussen jou tande en sluit jou lippe rondom die mondstuk, maar moenie dit byt nie. Net nadat jy begin om deur jou mond in te asem, moet jy die bokant van die inhaleerder druk om FOXAIR vry te stel, terwyl jy steeds bestendig en diep inasem.
5. Terwyl jy jou asem inhou, verwyder die inhaleerder van jou mond en jou vinger van die bokant van die inhaleerder. Hou aan om jou asem aan te hou vir solank as wat gemaklik is.
6. Om 'n tweede sproei te neem, hou die inhaleerder regop en wag vir ongeveer 'n halwe minuut voordat jy stappe 2 tot 5 herhaal.

Sit die dop van die mondstuk terug deur die dop ferm in te druk tot in sy posisie.

Let wel:

Moenie met stappe 4 en 5 haastig wees nie. Dit is belangrik dat jy begin om so stadig as moontlik in te asem net voordat jy jou inhaleerder aktiveer. Oefen voor 'n spieël vir die

eerste paar keer. As jy ŉ "miswolk" uit die bokant van jou inhaleerder of die kante van jou mond sien verskyn, behoort jy weer vanaf stap 2 te begin.

Indien jou dokter vir jou ander instruksies gegee het vir die gebruik van jou inhaleerder, volg dit asseblief versigtig. Vertel jou dokter indien jy enige probleme het.

Skoonmaak:

Jou inhaleerder moet ten minste een keer per week skoongemaak word.

1. Verwyder die dop van die mondstuk.
2. Moenie die kannetjie uit die plastiese omhulsel verwyder nie.
3. Vee die binnekant en die buitekant van die mondstuk en die plastiese omhulsel met ŉ droë doekie, snesie of wattestokkie af.
4. Sit die dop van die mondstuk weer op.

Moenie die metaalkannetjie in water sit nie.

Nadat jy jou inhaleerder gebruik het:

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

Indien jy meer FOXAIR INHALER gebruik as wat jy moet:

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 vergeet om FOXAIR INHALER te gebruik:

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

MOONTLIKE NEWE-EFFEKTE:

FOXAIR INHALER kan newe-effekte veroorsaak.

Sommige persone kan vir medisyne allergies wees. Indien jy enigeen van die volgende simptome kort na inname van FOXAIR INHALER 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.

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 beendensiteit, oogprobleme en vertraging van groei by kinders.

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

Nie alle newe-effekte wat vir hierdie medisyne aangemeld is, word in hierdie brosjure aangeteken nie. Indien jou algemene gesondheid agteruitgaan terwyl jy hierdie medisyne neem, moet jy asseblief jou dokter, apteker of ŉ ander gesondheidsorgkundige vir advies raadpleeg.

BERGING EN WEGDOENING VAN FOXAIR INHALER:

Onmiddellik na gebruik moet die dop van die mondstuk ferm teruggeplaas word en in sy posisie geskuif word tot ŉ klikgeluid gehoor word. Moenie oormatige krag gebruik nie.

Hou jou inhaleerder weg van hitte of direkte sonlig.

Hou jou inhaleerder ook weg van ryp, omdat dit jou medisyne se werking kan belemmer.

Die kannetjie moet nie geprik, gebreek of verbrand word nie, selfs al is dit leeg. Neem dit na jou naaste apteek om vernietig te word.

Moenie na die verval datum wat as 'Verv.' op die karton en etiket aangedui word, gebruik nie.

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

Hou alle medisyne buite sig van kinders.

Gee alle ongebruikte medisyne terug aan jou apteker.

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

AANBIEDING VAN FOXAIR INHALER:

Die suspensie word vervat in ŉ aluminiumallooi kannetjie wat verseël is met ŉ doseringsklep. Die kannetjies pas in plastiese aktiveerders wat ŉ 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 ŉ kartonhouer verpak.

IDENTIFIKASIE VAN FOXAIR INHALER:

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

REGISTRASIENOMMER:

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

NAAM EN ADRES VAN DIE REGISTRASIEHOUER:

GlaxoSmithKline South Africa (Edms) Bpk

Hawkinslaan 39

Epping Industria 1, 7460

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