FOXAIR® INHALER

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.

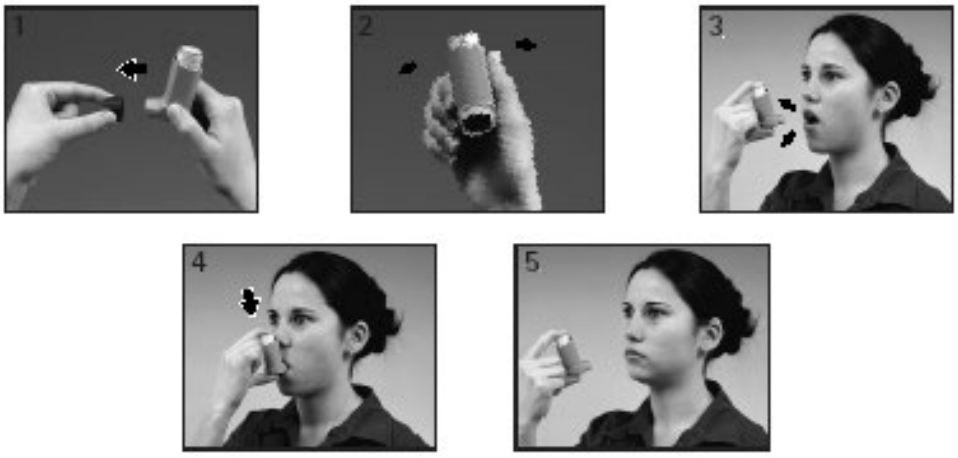
Instructions for use:

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

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