

GLAXOSMITHKLINE SOUTH AFRICA (PTY) LIMITED	Submission Date		Type	Clinical
FOXAIR 25/50; 25/125; 25/250 INHALER	Implementation Date	pending	Category	Reg 10 notification
POWDER FOR INHALATION (SALMETEROL/FLUTICASONE PROPIONATE)	Approval Date	26 Nov 2010	Reference	GDSv7
			CTD	v0006

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1.3.2 Proposed Patient information leaflet

1 Patient Information Leaflet

2

3 SCHEDULING STATUS:

4 S4

5

6 PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL [DOSAGE] FORM:

7 FOXAIR 25/50 INHALER

8 FOXAIR 25/125 INHALER

9 FOXAIR 25/250 INHALER

10 Metered-dose inhaler

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

12

13 **Read all of this leaflet carefully before you start using FOXAIR Inhaler.**

- 14
- 15 • Keep this leaflet. You may need to read it again.
 - 16 • If you have further questions, please ask your doctor or your pharmacist.
 - 17 • FOXAIR has been prescribed for you or your child personally and should not be shared
18 with other people. It may harm them, even if their symptoms are the same as yours.

18

19 WHAT FOXAIR INHALER CONTAINS:

20 The active substances are salmeterol and fluticasone propionate

21 Each single actuation of FOXAIR INHALER provides:

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

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

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26 **WHAT FOXAIR INHALER IS USED FOR:**

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

29

30 **BEFORE YOU USE FOXAIR INHALER:**

31 **Do not use FOXAIR:**

- 32 • if you are hypersensitive (allergic) to salmeterol xinafoate or fluticasone propionate or
33 the other ingredient of FOXAIR [INHALER].

34

35 **Take special care with FOXAIR INHALER:**

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

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

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

44

45 **Pregnancy and Breastfeeding:**

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

48

49 **Driving and using machinery:**

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50 FOXAIR INHALER is unlikely to produce an effect.

51

52 **Using other medicines with FOXAIR INHALER:**

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

56

57 **HOW TO USE FOXAIR INHALER:**

58 DO NOT use this medicine to treat a sudden attack of breathlessness as it will not help
59 you. You will need a different type of medicine, which you must not confuse with FOXAIR
60 INHALER.

61 You should always have your fast-acting 'rescue' medicine available. It is very important
62 that you use FOXAIR INHALER regularly every day.

63 Do not stop treatment even if you feel better unless told to do so by your doctor. Do not
64 change your dose unless told to by your doctor. If you are breathless or wheezing more
65 often than normal, tell your doctor.

66 The medicine in the FOXAIR INHALER should be inhaled into your lungs. FOXAIR
67 INHALER must only be breathed in through the mouth. If you have any difficulties or do not
68 understand the instructions ask your doctor or pharmacist.

69 Take your medicine as your doctor has told you. The label on it will usually tell you how
70 much to take and how often. If you are not sure ask your doctor or pharmacist.

71 **Shake the inhaler well before use.**

72 The usual dose is:

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73 **[ASTHMA]**

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

75 Two inhalations of FOXAIR 25/50 twice daily.

76 OR

77 Two inhalations of FOXAIR 25/125 twice daily.

78 OR

79 Two inhalations of FOXAIR 25/250 twice daily.

80

81 **Instructions for use:**

82 ***Testing your inhaler:***

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

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

88

89 ***Using your inhaler:***



90

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- 91 1. Remove the mouthpiece cover by gently squeezing the sides of the cover and
92 check the mouthpiece inside and outside to see that it is clean.
- 93 2. Shake the inhaler well.
- 94 3. Hold the inhaler upright between finger/s and thumb with your thumb on the base,
95 below the mouthpiece. Breathe out as far as is comfortable and then ...
- 96 4. Place the mouthpiece in your mouth between your teeth and close your lips around
97 it, but do not bite it. Just after starting to breathe in through your mouth press down
98 on the top of the inhaler to release FOXAIR, while still breathing in steadily and
99 deeply.
- 100 5. While holding your breath, take the inhaler from your mouth and take your finger
101 from the top of the inhaler. Continue holding your breath for as long as is
102 comfortable.
- 103 6. To take the second puff keep the inhaler upright and wait about half a minute before
104 repeating steps 2 to 5.

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

106 **Important:**

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

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

113

114 **Cleaning:**

115 Your inhaler should be cleaned at least once a week.

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

121 Do not put the metal canister into water.

122

123 ***After using your inhaler:***

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

126

127 **If you use more FOXAIR INHALER than you should:**

128 If you accidentally take a larger dose than recommended you may notice that your heart is
129 beating faster than usual and that you feel shaky.

130 Other symptoms you may experience include headache, muscle weakness and aching
131 joints.

132 Tell your doctor as soon as possible if you accidentally take a larger dose than you were
133 told to.

134

135 **If you forget to take FOXAIR INHALER:**

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

137

138 **POSSIBLE SIDE EFFECTS:**

139 FOXAIR INHALER can have side effects.

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

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

146 Some people very occasionally find that their mouth, throat or tongue becomes sore or that
 147 their voice becomes hoarse after inhaling this medicine. Gargling with water and spitting it
 148 out immediately after each dose may help. Tell your doctor but do not stop treatment
 149 unless told to do so.

150 Also tell your doctor if you have any of the following symptoms: headache, muscle cramps,
 151 pains in joints, skin rash or trembling, increase in pulse rate.

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

154 Rounded face, loss of bone density, eye problems and slowing of growth in children.

155 If you have any other symptoms that you do not understand, tell your doctor or pharmacist.

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

159

160 **STORING AND DISPOSING OF FOXAIR INHALER:**

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

163 Keep your inhaler away from heat or direct sunlight.

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

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

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

168 Store in a dry place below 30 °C.

169 Store all medicines out of sight of children.

170 Return all unused medicine to your pharmacist.

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

172

173 **PRESENTATION OF FOXAIR INHALER:**

174 The suspension is contained in an aluminium alloy can sealed with a metering valve. The
175 canisters are fitted into plastic actuators incorporating an atomising orifice and fitted with
176 dustcaps. FOXAIR INHALER has been formulated in three strengths and one pack size,
177 delivering 120 actuations per inhaler. FOXAIR INHALER is packed in a carton.

178

179 **IDENTIFICATION:**

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

182

183 **REGISTRATION NUMBER:**

184 FOXAIR 25/50 INHALER – 42/21.5.4/0244

185 FOXAIR 25/125 INHALER – 42/21.5.4/0245

186 FOXAIR 25/250 INHALER – 42/21.5.4/0246

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188 **NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF**

189 **REGISTRATION:**

190 GlaxoSmithKline South Africa (Pty) Ltd

191 39 Hawkins Avenue

192 Epping Industria 1, 7460

193

194 **DATE OF PUBLICATION [~~OF THE PATIENT INFORMATION LEAFLET~~]:**

195 26 November 2010

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199 **HISTORY:**

200

201 Compliant PI submitted to MCC 28 June 2010

202 PIL aligned with MCC letter dated 25 August 2010

203 Registered 26 November 2010

204 Annotated 7 Dec 2010 – Applicant change to GSK

205 **Amended: 10 Dec 2015 (Notification to bring in line with Reg 9 & !0). Implement 11 Dec 2015**