

GLAXOSMITHKLINE SOUTH AFRICA (PTY) LIMITED	Submission Date	10 Dec 2015	Type	Clinical
FOXAIR 50/100; 50/250; 50/500 ACCUHALER	Implementation Date	pending	Category	Reg 10 notification
POWDER FOR INHALATION (SALMETEROL/FLUTICASONE PROPIONATE)	Approval Date	pending	Reference	GDSv10
			CTD	v0006

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1.3.2 Patient information leaflet

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.

The other ingredient is lactose (which contains milk protein).

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.

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26 **BEFORE YOU USE SERETIDE ACCUHALER:**

27 **Do not use SERETIDE Accuhaler:**

- 28 • if you are allergic to salmeterol xinafoate
- 29 • if you are allergic to fluticasone propionate
- 30 • if you are allergic to lactose or milk proteins.

31

32 **Take special care with FOXAIR ACCUHALER:**

33 Special care should be taken with FOXAIR:

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

38

39 **Pregnancy and Breastfeeding:**

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

42

43 **Important information about some of the ingredients of FOXAIR Accuhaler:**

44 Each blister of powder contains lactose. Patients with rare hereditary problems of galactose
45 intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take
46 this medicine.

47

48 **Using other medicines with FOXAIR Accuhaler:**

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

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

54

55 HOW TO USE FOXAIR ACCUHALER:

56 DO NOT use this medicine to treat a sudden attack of breathlessness as it will not help you.

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

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

68 The usual dose is:

69 Asthma:

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

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

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

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

74 Children 4 years and older:

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

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77 **COPD:**

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

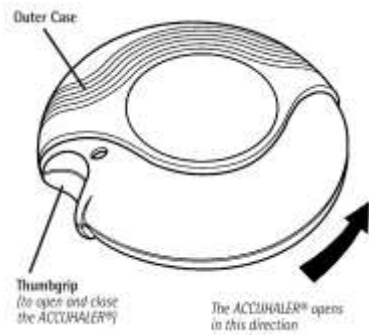
80

81 **Instructions for use of your FOXAIR Accuhaler:**

82 ***Use and Handling:***

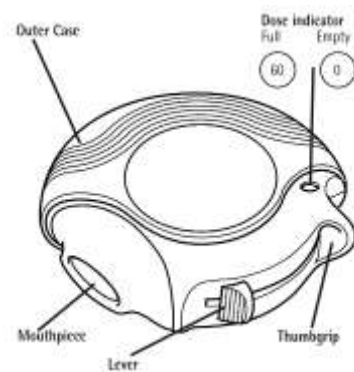
83 The Accuhaler releases a powder which is inhaled into the lungs. A dose indicator on the
84 Accuhaler indicates the number of doses left.

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



86

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



89

90 This Accuhaler contains 60 individually protected doses of your medicine, in powder form.
91 Each dose is accurately measured and hygienically protected. It requires no maintenance -

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92 and no refilling. The dose indicator on top of your Accuhaler tells you how many doses are
93 left. Numbers 5 to 0 will appear in RED, to warn you when there are only a few doses left.
94 The Accuhaler is easy to use. When you need a dose, just follow the four simple steps
95 illustrated

- 96 1. Open.
- 97 2. Slide.
- 98 3. Inhale.
- 99 4. Close.

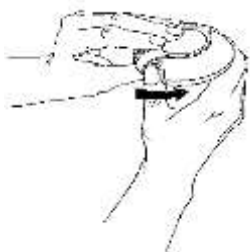
100

101 ***How your Accuhaler works:***

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

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

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



109

110 **2. Slide.**

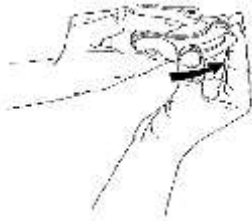
111 Hold your Accuhaler with the mouthpiece towards you. Slide the lever away from you, as
112 far as it will go - until it clicks. Your Accuhaler is now ready to use. Every time the lever

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113 is pushed back, a dose is made available for inhaling. This is shown by the dose
114 counter. Do not play with the lever as this releases doses which will be wasted.



115

116 **3. Inhale.**

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

118 Hold the Accuhaler away from your mouth.

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

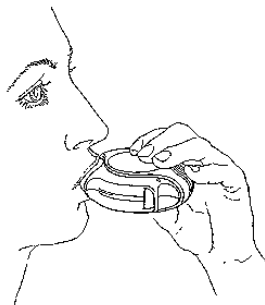
120 Put the mouthpiece to your lips.

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

122 Remove the Accuhaler from your mouth.

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

124 Breathe out slowly.



125

126 **4. Close.**

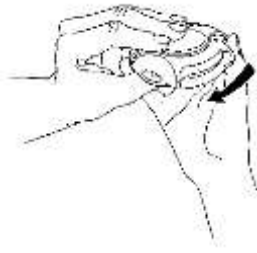
127 To close your Accuhaler, put your thumb in the thumbgrip, and slide the thumbgrip back
128 towards you, as far as it will go.

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

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

134

135 ***Remember:***

136 Keep your Accuhaler dry.

137 Keep it closed when not in use.

138 Never breathe into your Accuhaler.

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

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

141

142 ***After using your Accuhaler:***

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

145

146 **If you use more FOXAIR Accuhaler than you should:**

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

151

152 **If you missed a dose of FOXAIR Accuhaler:**

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

154

155 **POSSIBLE SIDE EFFECTS:**

156 FOXAIR can have side effects.

157 Not all side effects reported for FOXAIR are included in this leaflet. Should your general

158 health worsen or if you experience any untoward effects while using FOXAIR, please

159 consult your doctor, pharmacist or other healthcare professional for advise.

160 Some people can be allergic to medicines. If you have any of the following symptoms soon

161 after taking FOXAIR Accuhaler, STOP taking this medicine and tell your doctor immediately.

162 • Sudden wheeziness and chest pain or tightness.

163 • Swelling of eyelids, face, lips, tongue or throat.

164 • Lumpy skin rash or "hives" anywhere on the body.

165 The above are all very serious side effects. If you have them, you may have had a serious

166 allergic reaction to FOXAIR. You may need urgent medical attention, or hospitalisation.

167 Some people very occasionally find that their mouth, throat or tongue becomes sore or that

168 their voice becomes hoarse after inhaling this medicine. Gargling with water and spitting it

169 out immediately after each dose may help. Tell your doctor but do not stop treatment unless

170 told to do so. Also tell your doctor if you have any of the following symptoms: headache,

171 muscle cramps, pains in joints, skin rash or trembling, increase in pulse rate.

172 It is possible that some patients, particularly those taking higher doses of this type of

173 medication, may very rarely suffer from the following side effects:

174 Rounded face, loss of bone density, eye problems and slowing of growth in children. If you

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

176

177 **STORING AND DISPOSING OF FOXAIR ACCUHALER:**

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178 Store in a dry place below 30 °C.

179 Store all medicines out of reach of children.

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

181 Return all unused medicine to your pharmacist.

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

183

184 PRESENTATION OF FOXAIR ACCUHALER:

185 A single Accuhaler is packed into a carton.

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

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

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

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

191 The device contains a dose counter which shows the number of doses remaining (60 to 1).

192 To show when the last five doses have been reached, the number appears in red.

193

194 IDENTIFICATION OF FOXAIR ACCUHALER:

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

196

197 REGISTRATION NUMBER:

198 FOXAIR 50/100 Accuhaler – 42/21.5.4/0581

199 FOXAIR 50/250 Accuhaler – 42/21.5.4/0582

200 FOXAIR 50/500 Accuhaler – 42/21.5.4/0583

201

202 NAME AND ADDRESS OF THE REGISTRATION HOLDER:

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203 GlaxoSmithKline South Africa (Pty) Ltd

204 39 Hawkins Avenue

205 Epping Industria 1, 7460

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207 **DATE OF PUBLICATION:**

208 4 June 2010

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GDS-10

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215 **HISTORY:**

216 Registered: 4 June 2010

217 **Amended: 10/12/2015 (Notification to bring in line with Reg 9 and 10)**

218