

27 **1. WHAT VOXRA XL IS AND WHAT IT IS USED FOR:**

28 VOXRA XL is a medicine prescribed by your doctor to treat your depression. It's thought to
29 interact with chemicals in the brain called noradrenaline and dopamine, which are linked
30 with depression.

31 **It may take a while before you start feeling better.** It takes time for VOXRA XL to have
32 its full effect, sometimes weeks or months. When you do start feeling better, your doctor
33 may advise you to keep taking VOXRA XL to prevent depression coming back.

34 **Your doctor has chosen this medicine to suit you and your condition.** Don't pass it on
35 to others. Before deciding on treatment with VOXRA XL, you and your doctor will probably
36 have discussed the risks of harm and the benefits that it is likely to have for you. This leaflet
37 will help you to take VOXRA XL safely.

38

39 **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE VOXRA XL:**

40 **Do not take VOXRA XL:**

- 41 • if you know that you are allergic to VOXRA XL, bupropion, or any of the other
42 ingredients in VOXRA XL tablets
- 43 • if you are taking any other medicines which contain bupropion
- 44 • if you have been diagnosed with epilepsy
- 45 • if you have brain tumour
- 46 • if you have an eating disorder, or used to (e.g. bulimia or anorexia nervosa)
- 47 • if you are usually a heavy drinker who has just stopped or are about to stop drinking
- 48 • if you recently stopped taking tranquillisers or sedatives, or if you are going to stop them
49 while you're taking VOXRA XL
- 50 • if you have been taking other medicines for depression called monoamine oxidase
51 inhibitors (MAOIs) in the last 14 days

- 52 • if you are pregnant or breastfeeding
- 53 • if you are less than 18 years of age. There is an increased risk of suicidal thoughts and
- 54 behaviour when children under 18 years of age are treated with antidepressants.

55 If any of these applies to you, talk to your doctor straight away, without taking VOXRA XL.

56

57 **Warnings and precautions:**

58 **Take special care with VOXRA XL:**

59 ***Talk to your doctor before taking VOXRA XL:***

- 60 • if you've ever had any fits or seizures in the past
- 61 • if you have a brain tumour
- 62 • if you have liver or kidney problems
- 63 • if you regularly drink a lot of alcohol
- 64 • if you have diabetes for which you use insulin or tablets
- 65 • if you have had any mental illness other than depression
- 66 • if you have had a serious head injury
- 67 • if you are over 65 years of age
- 68 • if you are pregnant or plan to become pregnant soon.
- 69 • if you suffer from high blood pressure

70 If any of the above applies to you, your doctor may want to pay special attention to your

71 care, or recommend another treatment.

72

73 ***Thoughts of suicide or worsening of your condition:***

74 If you are depressed, you can sometimes have thoughts of harming or killing yourself.

75 These thoughts may be increased when first starting antidepressants. These medicines all

76 take time to work - usually about two weeks, but sometimes longer.

77 You may be more likely to think like this:

78 - if you have previously had thoughts about killing or harming yourself

79 - if you are under 25 years old.

80 If you have thoughts of harming or killing yourself at any time: Get medical advice as soon
81 as possible (from a doctor or at a hospital).

82

83 **Other medicines with VOXRA XL:**

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

86 If you have been taking other medicines for depression called monoamine oxidase inhibitors
87 (MAOIs) in the last 14 days, tell your doctor without taking VOXRA XL.

88 If you are taking any other medicines, herbs or vitamins, including products you bought
89 yourself, tell your doctor. He or she may alter your dose of VOXRA XL, or suggest a
90 change in your other medications.

91 Some medicines don't mix with VOXRA XL. Some of them may increase the chance of
92 seizures (fits). Other medicines may increase the risk of other side effects. Some examples
93 are listed below, but it is not an exhaustive list.

94

95

96 ***There may be a higher than usual chance of seizures (fits):***

97 • if you take medicines which make seizures (fits) more likely e.g. theophylline for
98 asthma or lung disease, tramadol a strong painkiller

99 • if you have been taking tranquillisers or sedatives, or if you are going to stop them while
100 you're taking VOXRA XL

101 • if you take stimulants or other medicines to control your weight or appetite.

102 If any of these applies to you, talk to your doctor straight away, before taking VOXRA XL.

103

104 ***There may be a higher than usual chance of other side effects:***

- 105 • if you take certain other medicines for depression or other mental illness
- 106 • if you take medicines for Parkinson's disease (levodopa, amantadine or
107 orphenadrine)
- 108 • if you take medicines used for epilepsy (carbamazepine, phenytoin, phenobarbitone)
- 109 • if you take cyclophosphamide or ifosfamide, mainly used to treat cancer
- 110 • if you take ticlopidine or clopidogrel, mainly used to prevent stroke
- 111 • if you take some beta blockers
- 112 • if you take medicines for heart rhythm
- 113 • if you use nicotine patches to help you stop smoking.

114 If any of these applies to you, talk to your doctor straight away, before taking VOXRA XL.

115

116 ***VOXRA XL may make other medicines less effective:***

117 If you take digoxin for your heart, tell your doctor. Your doctor may consider adjusting the
118 dose of digoxin.

119

120 **VOXRA XL with food, drink and alcohol:**

121 ***Drinking alcohol:*** Some people find they are more sensitive to alcohol when taking VOXRA
122 XL and your doctor may suggest you do not drink alcohol (beer, wine or spirits) while taking
123 VOXRA XL, or try to drink very little. But if you drink a lot now, do not stop suddenly: it may
124 be risky. Talk to the doctor about drinking before you start taking VOXRA XL.

125

126 ***Effect on urine tests***

127 VOXRA XL may interfere with some urine tests to detect other drugs. If you require a urine
128 test, tell your doctor that you are taking VOXRA XL.

129

130 **Pregnancy, breastfeeding and fertility:**

131 If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or
132 other healthcare professional for advice before taking VOXRA XL.

133 If you are pregnant, or think you could be, or if you are planning to become pregnant do not
134 take VOXRA XL without checking with your doctor. Studies have reported an increase in
135 the risk of birth defects, particularly heart defects, in babies whose mothers were taking
136 VOXRA XL.

137

138 **Driving and using machinery:**

139 If VOXRA XL makes you dizzy or light-headed, do not drive or operate any tools or
140 machines.

141

142 **3. HOW TO TAKE VOXRA XL:**

143 Always take VOXRA exactly as your doctor has instructed you. You should check with your
144 doctor or pharmacist if you are unsure.

145

146 **How much to take:**

147 The usual starting dose for adults is one 150 mg tablet every day.

148 Your doctor may increase your dose to 300 mg once a day if your depression does not
149 improve after several weeks.

150 Take your dose of VOXRA XL early in the morning.

151 Do not take VOXRA XL more than once each day.

152

153 **Your doctor may alter your dose:**

- 154 • if you have liver or kidney problems
155 • if you are over 65 years of age.

156

157 **Swallow the tablets whole.** Do not chew them, crush them or split them – if you do, the
158 medicine will be released into your body too quickly. If this happens you may be more likely
159 to get side effects including seizures (fits).

160

161 **Always take VOXRA XL exactly as your doctor has advised you.** These are the usual
162 doses, but your doctor's advice is personal to you. Check with your doctor or pharmacist if
163 you are unsure.

164

165 **How long to take it for:**

166 Only you and your doctor can decide how long you should take VOXRA XL. It may take
167 weeks or months of treatment for you to see any improvement. Discuss your symptoms
168 with your doctor regularly to decide how long you should be taking it. When you do start
169 feeling better your doctor may advise you to keep taking VOXRA XL to prevent depression
170 coming back. Do not stop taking VOXRA XL or reduce your dose without talking to your
171 doctor first.

172 Sometimes VOXRA XL tablets have an unusual smell. This is normal: carry on taking the
173 tablets as usual.

174

175 **If you take more VOXRA XL than you should:**

176 If you take too many tablets, you may increase the risk of a seizure (fit).

177 Other serious effects may also happen. **Don't delay.** Ask your doctor what to do or contact
178 your nearest hospital emergency department at once.

179

180 **If you forget to take VOXRA XL:**

181 If you miss a dose, wait and take your next tablet at the usual time. **Do not take a tablet to**
182 **catch up** for the dose you forgot.

183

184 **4. POSSIBLE SIDE EFFECTS:**

185 VOXRA XL can have side effects.

186 Not all side effects reported for VOXRA XL are included in this leaflet. Should your general
187 health worsen or if you experience any untoward effects while taking this medicine, please
188 consult your doctor, pharmacist or other healthcare professional for advice.

189

190 **Seizures (fits):**

191 Approximately 1 in every 1 000 people taking the maximum dose of VOXRA XL is at risk of
192 a seizure (fit). The chance of this happening is higher if you take too much, if you take
193 certain medicines in combination with VOXRA XL, or if you are at higher than usual risk of
194 seizures (fits). If you are worried, talk to your doctor. If you have a fit, tell your doctor when
195 you have recovered. Don't take any more tablets.

196

197 **Allergic reactions:**

198 Some people may get allergic reactions to VOXRA XL. These include:

- 199 • red skin or rash (like nettle rash), blisters or itchy lumps (hives) on the skin. Some skin
200 rashes may need hospital treatment, especially if you also have a sore mouth or sore
201 eyes

- 202 • unusual wheezing or difficulty in breathing
- 203 • swollen eyelids, lips or tongue
- 204 • pains in muscles or joints
- 205 • collapse or blackout.

206 If you have any signs of an allergic reaction contact a doctor at once. Don't take any more
207 tablets. Allergic reactions can last a long time. If your doctor prescribes something to help
208 with allergic symptoms, make sure you finish the course.

209

210 **Other side effects:**

211 ***Disturbed sleep:*** The most common side effect in people taking VOXRA XL is difficulty
212 sleeping. Make sure you take your tablet early in the morning.

213

214 ***Other common side effects:***

- 215 • headache, fever, dizziness, itching, sweating, skin rash, hives
- 216 • shakiness, tremor, chest pain
- 217 • feeling anxious or, agitated
- 218 • dry mouth, tummy pain or other upsets (feeling sick, vomiting, constipation), changes in
219 the taste of food, loss of appetite
- 220 • changes in blood pressure, flushing
- 221 • ringing in the ears, visual disturbances.

222

223 ***Uncommon side effects:***

- 224 • weakness, tiredness
- 225 • feeling depressed
- 226 • feeling confused

- 227 • difficulty concentrating
- 228 • raised heart rate
- 229 • weight loss.

230

231 ***The following side effects may occur:***

- 232 • seizures (fits)
- 233 • palpitations, fainting
- 234 • uncontrolled movements, twitching, muscle stiffness, problems with walking or
- 235 coordination
- 236 • feeling restless, irritable, hostile, aggressive or paranoid, feeling unreal or strange
- 237 (depersonalisation), sensing or believing things that are not there
- 238 (hallucinations/delusions), strange dreams, tingling or numbness, loss of memory
- 239 • raised liver enzymes, yellowing of skin or the whites of your eyes (jaundice), hepatitis
- 240 • severe allergic reactions; rash together with joint and muscle pains, worsening of
- 241 psoriasis
- 242 • changes in blood sugar levels
- 243 • urinating more or less than usual, uncontrollable urination

244 Talk about any troublesome side effects with your doctor or pharmacist. If you notice any
245 side effects not listed in this leaflet, please tell your doctor or pharmacist.

246

247 **Thoughts of suicide or worsening of your condition:**

248 If you are depressed you can sometimes have thoughts of harming or killing yourself. These
249 thoughts may be increased when first starting antidepressants. These medicines can take
250 time to work - usually about two weeks, but sometimes longer (see 'Take special care with
251 VOXRA XL').

252

253 **Children under 18 years of age:**

254 VOXRA XL should not be used to treat children under 18 years of age. There is an
255 increased risk of suicidal thoughts and behaviour when children under 18 years of age are
256 treated with antidepressants.

257

258 **Reporting of side effects:**

259 If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side
260 effects to SAHPRA via the '6.04 Adverse Drug Reaction Reporting Form', found on-line
261 under SAHPRA'S publications: <http://www.sahpra.org.za/Publications/Index/8>. By reporting
262 side effects, you can help provide more information on the safety of VOXRA XL

263

264 **5. HOW TO STORE VOXRA XL:**

265 Keep out of the reach and sight of children.

266 Store at or below 25 °C. Keep well closed.

267 Store it in the original pack, out of direct sunlight.

268 Do not use after the expiry date stamped on the outer pack.

269 If you have any VOXRA XL left over once you've finished treatment, take them back to the
270 pharmacist.

271

272 **6. CONTENTS OF THE PACK AND OTHER INFORMATION:**

273 **What VOXRA XL contains:**

274 Each VOXRA XL 150 tablet contains 150 mg of bupropion hydrochloride.

275 Each VOXRA XL 300 tablet contains 300 mg of bupropion hydrochloride.

276 The other ingredients are:

277 Tablet core: Polyvinyl alcohol, glyceryl behenate
278 Film-coat: Ethylcellulose 100, povidone, polyethylene glycol 1450, methacrylic acid
279 copolymer dispersion (Eudragit L30 D-55), silicon dioxide, triethyl citrate, edible black ink
280 (for printing)

281

282 **What VOXRA XL looks like and contents of the pack**

283 VOXRA XL 150 mg: Creamy white to pale yellow, round tablet, imprinted with 'GS5FV' in
284 black ink on one side and the other side plain.

285 VOXRA XL 300 mg: Creamy white to pale yellow, round tablet, imprinted with 'GS5YZ' in
286 black ink on one side and the other side plain.

287

288 White opaque plastic HDPE bottles with white polypropylene plastic child-resistance
289 closures, containing 30 tablets.

290

291 **Registration Number:**

292 VOXRA XL 150: 41/1.2/0373

293 VOXRA XL 300: 41/1.2/0374

294

295 **Holder of Certificate of Registration and Manufacturer:**

296 GlaxoSmithKline South Africa (Pty) Ltd

297 39 Hawkins Avenue

298 Epping Industria 1, 7460

299

300 **This leaflet was last revised in:** 24 October 2019

301

GDS-17+22

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303

304 **AMENDMENT HISTORY**

305

306 Proposed: May 2006

307 Amended: 16 August 2007 (in response to CC Recommendations dated 23/02/07)

308 Amended: 14 February 2008 (in line with CCC recommendations dated 14/12/2007)

309 Amended: 22 April 2008 (In response to P&A recommendations dated 28/02/2008) – Registered 17/04/09

310 Amended: 26 February 2009 (Proprietary name change to approved name Voxra XL)

311 Amended: 17 May 2012 (applicant address to CT)

312 Amended: 25 October 2012 (USRN to include pregnancy data) – annotated

313 Amended: 24 January 2012 (USRN: Response to CCC recommendations dated 22/11/2012) – approved 01 March 2013

314 Amended: 8 May 2018 (Notification to bring in line with Regulation 9 of Act 101/1965 as amended). Implemented 9 May 2018

316 Amended: 22 August 2019 (reformatting to new draft PI/PIL guidelines of compliant response submitted 08/05/2018)

317 **Amended: 15 October 2019 (compliant response submitted in response to CCCR received 04.10.2019)**