

GLAXOSMITHKLINE SOUTH AFRICA (PTY) LIMITED	Submission Date	06 SEPTEMBER 2018	Type	B
REQUIP XL	Implementation Date	06 OCTOBER 2018	Category	3
PROLONGED RELEASE TABLET 2 mg/4 mg/8 mg			Reference	D2017-2019, v0004

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1
2

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3 **SCHEDULING STATUS:**

4 **S4**

5

6 **PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:**

7 **REQUIP® XL 2 mg** Prolonged Release tablets

8 **REQUIP® XL 4 mg** Prolonged Release tablets

9 **REQUIP® XL 8 mg** Prolonged Release tablets

10

11 Read all of this leaflet carefully before you start taking REQUIP XL.

- 12
- Keep this leaflet. You may need to read it again.
 - If you have further questions, please ask your doctor or pharmacist.
 - REQUIP XL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

17

18 **WHAT REQUIP XL CONTAINS:**

19 REQUIP XL 2 mg: Each tablet contains 2,0 mg ropinirole as the hydrochloride and sugar
20 (lactose 46,32 mg and mannitol 73,16 mg).

21 REQUIP XL 4 mg: Each tablet contains 4,0 mg ropinirole as the hydrochloride and sugar
22 (lactose 44,04 mg and mannitol 73,16 mg).

23 REQUIP XL 8 mg: Each tablet contains 8,0 mg ropinirole as the hydrochloride and sugar
24 (lactose 39,48 mg and mannitol 73,16 mg).

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26 **Excipients (Inactive ingredients):**

27 **Tablet core:** Hypromellose 2208, hydrogenated castor oil, carboxymethylcellulose sodium,
28 povidone, maltodextrin, magnesium stearate, lactose monohydrate (see above), colloidal
29 silicon dioxide, mannitol (E421) (see above), ferric oxide yellow (E172), glyceryl behenate.

30 See "BEFORE YOU TAKE REQUIP XL: Important information about some of the
31 ingredients of REQUIP XL".

32

33 **Film coat:** The tablet strengths of REQUIP XL are distinguished by colour therefore, the
34 composition of the film coat varies. All film coats contain hydroxypropyl methylcellulose,
35 titanium dioxide and polyethylene glycol, other variations are shown below:

36 2 mg: ferric oxide yellow (E172) and ferric oxide red (E172).

37 4 mg: sunset yellow (E110) and indigo carmine (E132).

38 8 mg: ferric oxide yellow (E172), ferric oxide black (E172), and ferric oxide red (E172).

39

40 See "BEFORE YOU TAKE REQUIP XL: Important information about some of the
41 ingredients of REQUIP XL".

42

43 **WHAT REQUIP XL IS USED FOR:**

44 REQUIP XL is used to treat Parkinson's disease.

45 REQUIP XL belongs to a group of medicines called dopamine agonists. Dopamine agonists
46 act in a similar way to the natural dopamine, so helping to reduce the symptoms of
47 Parkinson's disease.

48 You may receive REQUIP XL on its own, but it may also be given with another medicine
49 used to treat Parkinson's disease (L-dopa) to make that medicine work better.

50

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51 **BEFORE YOU TAKE REQUIP XL:**

52 **Do not take REQUIP XL:**

- 53 • if you are allergic (hypersensitive) to ropinirole or any REQUIP XL ingredients listed
- 54 above
- 55 • if you have previously taken REQUIP XL and became unwell, tell your doctor before
- 56 taking these tablets
- 57 • if you become unwell while you are taking your tablets, tell a doctor at once
- 58 • if you have severe kidney disease.

59

60 **Take special care with REQUIP XL:**

61 Tell your doctor before you start taking REQUIP XL

- 62 • if you are under 18
- 63 • if you have heart disease
- 64 • if you have liver disease
- 65 • if you have kidney disease
- 66 • if you are intolerant to some sugars (e.g. lactose)
- 67 • if you have a serious mental health problem such as schizophrenia, hallucinations
- 68 (seeing or hearing things that aren't really there) or irrational ideas (delusions), or have
- 69 had one in the past
- 70 • if you have experienced any unusual urges and/or behaviours (such as excessive
- 71 gambling or excessive sexual behaviour), tell your doctor before you start taking your
- 72 tablets.

73 Check with your doctor if you think any of these apply to you. Your doctor will decide

74 whether REQUIP XL is suitable for you.

75

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76 **Unusual urges or behaviours:** Tell your doctor if you or your family notices that you are
77 behaving in a way that is unusual for you. Examples of this are an unusual urge to gamble
78 or increased sexual urges or behaviours while you are taking REQUIP XL.

79

80 **REQUIP XL and L-dopa:** When treating Parkinson's disease, REQUIP XL can be taken on
81 its own, or with another medicine called L-dopa (also called levodopa). If you are taking L-
82 dopa you may experience some uncontrolled jerky when you start taking REQUIP XL. Tell
83 your doctor if this happens, as your dose of L-dopa may need to be reduced.

84

85 **Pregnancy and breastfeeding:**

86 If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or
87 other healthcare professional for advice, before taking REQUIP XL.

88 **Pregnancy:** You should not take REQUIP XL when pregnant unless your doctor tells you
89 to.

90

91 **Breastfeeding:** You should not take REQUIP XL when breastfeeding.

92

93 **Driving and using machines:**

Falling Asleep During Activities of Daily Living:

Patients treated with REQUIP XL have reported falling asleep while engaged in activities of daily living, including the operation of motor vehicles which sometimes resulted in accidents. Although many of these patients reported somnolence (extreme sleepiness) while on REQUIP XL, some said that they had no warning signs of excessive drowsiness and believed that they were alert immediately prior to falling asleep. Some of these events have been reported as late as one year after starting treatment with REQUIP XL.

Somnolence (extreme sleepiness) is a common occurrence in patients receiving REQUIP XL. Many clinical experts believe that falling asleep while engaged in activities of daily living always occurs in patients with a history of somnolence, although many patients

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may not give such a history. For this reason, your doctor will continually assess you for any signs of drowsiness or sleepiness, especially since these events may occur some time after starting treatment.

Before starting treatment with REQUIP XL, your doctor will advise you on the possibility that you may develop drowsiness and your doctor will ask you questions about the risk factors that may increase this risk e.g. if you are taking other medicines which make you drowsy, any medication that help you sleep, if you have a sleeping disorder, and if you are taking other medicines that increase the levels of ropinirole (active ingredient of REQUIP XL) in your blood (e.g. antibiotics containing ciprofloxacin).

After starting REQUIP XL, if you start to suffer from extreme sleepiness or suddenly begin falling asleep while doing activities that require your active participation (e.g. conversations, eating), do not drive or use machinery and avoid all dangerous activities.

Tell your doctor immediately who will reassess your situation and advise you on what to do next.

94

95 Important information about some of the ingredients of REQUIP XL:

96 REQUIP XL contains lactose. Patients with the rare hereditary conditions of lactose or
97 galactose intolerance should not take REQUIP XL. Lactose may have an effect on the
98 control of your blood sugar if you have diabetes mellitus.

99 REQUIP XL 3 mg and 4 mg tablets contain a colouring called sunset yellow (E110), this
100 may cause allergic reactions in some people.

101

102 Taking other medicines with REQUIP XL:

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

105 Tell your doctor if:

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- 106 • you have allergies to any other medicines or substances, such as dyes, foods or
107 preservatives (see 'Important information about some of the inactive ingredients' below)
- 108 • you are taking any prescription or OTC (over-the-counter) medicines or any medicine
109 you have bought from a supermarket or health food shop
- 110 • you are taking any of the following medicines:
- 111 - medicines to treat psychiatric conditions
- 112 - medicines for the lowering of blood pressure or for heart problems
- 113 - antibiotics
- 114 - medicines for asthma, bronchitis or emphysema
- 115 - hormone replacement therapy
- 116 - a medicine called metoclopramide usually taken for digestive disorders
- 117 - other medicines for Parkinson's disease.

118 Because REQUIP XL can make you feel sleepy, tell your doctor or pharmacist if you are
119 taking any other medicines that also make you feel sleepy e.g. tranquilisers, sleeping tablets
120 and antidepressants.

121 You should not drink alcohol while you are taking REQUIP XL.

122

123 HOW TO TAKE REQUIP XL:

124 Do not share medicines prescribed for you with any other person.

125 Follow the doctor's instructions about how and when you take your tablets. Your doctor will
126 decide how many tablets you need to take each day and you should always follow his/her
127 instructions. When you first start taking REQUIP XL, the amount you take will be increased
128 gradually.

129 Your doctor may increase or decrease the amount that you are taking to give you the
130 maximum benefit from the medicine. You will be told to take REQUIP XL once daily and at
131 a similar time each day.

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132 You must swallow the tablet whole with water. The tablets must not be chewed, crushed or
133 broken. You can take REQUIP XL with or without food.

134 If you are taking other medicines for Parkinson's disease, the doctor may decrease the dose
135 of these medicines whilst you are taking REQUIP XL.

136 You should continue to take your medicine even if you do not feel better, as it may take a
137 number of weeks for your medicine to work.

138 Please read the label carefully. If you have any questions about your medicine and how to
139 take it, please ask the doctor or pharmacist.

140 If you are taking L-dopa, you may experience some uncontrollable movements (dyskinesias)
141 when you start taking REQUIP XL. Tell your doctor if this happens, as your doctor may need
142 to adjust the doses of the medicines you are taking.

143 Tell your doctor if you or your family notices that you are developing any unusual behaviours
144 (such as an unusual urge to gamble or increased sexual urges and/or behaviours) while you
145 are taking REQUIP XL. Your doctor may need to adjust or stop your dose.

146

147 If you stop taking REQUIP XL:

148 Do not stop taking REQUIP XL unless your doctor tells you to. Your doctor will tell you the
149 safest way to stop taking REQUIP XL.

150

151 If you take more REQUIP XL than you should:

152 In the event of overdosage, consult your doctor or pharmacist. If neither is available,
153 contact the nearest hospital or poison control centre.

154 Show the doctor your pack of tablets.

155

156 If you forget to take REQUIP XL:

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157 If you have forgotten to take REQUIP XL for one day or more, consult your doctor for advice
158 on restarting REQUIP XL. Do not take extra doses to make up for forgotten individual
159 doses.

160

161 **POSSIBLE SIDE EFFECTS:**

162 Side effects with REQUIP XL include:

163 Frequent side effects:

- 164 • feeling drowsy
- 165 feeling sick (nausea)
- 166 • fainting
- 167 • experiencing hallucinations
- 168 • dizziness (or spinning sensation)
- 169 • swelling of the hands, ankles or feet
- 170 • constipation
- 171 • **a drop in blood pressure that may make you feel dizzy or faint especially when**
- 172 **standing up from a sitting or lying position**
- 173 • being sick (vomiting)
- 174 • dyspepsia (e.g. feeling full up and bloated, experiencing heartburn)
- 175 • stomach pain.

176

177 Less frequent side effects:

- 178 • other psychotic reactions in addition to hallucinations, such as severe confusion
- 179 (delirium), irrational ideas (delusions) and irrational suspiciousness (paranoia)
- 180 • increased sexual desire

• Some patients taking REQUIP XL have shown urges to behave in a way unusual for

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them. Examples of this are an unusual urge to gamble or increased sexual urges and/or behaviours. Tell your doctor as soon as possible if you notice any of these changes in your behaviour. Your doctor may need to adjust or stop your dose.

181

182 Other side effects include:

- 183
- 184 • fall asleep suddenly without apparently feeling sleepy. If you feel extremely tired during
185 the day or fall asleep suddenly without apparently feeling sleepy you should see your
186 doctor
 - 187 • allergic reactions such as red, itchy swellings on the skin (hives), swelling of the face,
188 lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, rash
189 or intense itching.

189

190 When REQUIP XL is taken with levodopa/L-dopa you may also experience the following
191 side effects:

- 192
- 193 • uncontrollable movements (dyskinesias) are a frequent side effect. If you are taking L-
194 dopa you may experience some uncontrollable movements (dyskinesias) when you start
195 taking REQUIP XL. Tell your doctor if this happens, as your doctor may need to adjust
196 the doses of the medicines you are taking.

196 Not all side effects reported for this medicine are included in this leaflet. Should your
197 general health worsen or if you experience any untoward effects while taking this medicine,
198 please consult your doctor, pharmacist or other health care professional for advice.

199

200 STORING AND DISPOSING OF REQUIP XL:

201 Store at or below 25 °C. Store in original package.

202 The expiry date of this medicine is printed on the label. Do not use the medicine after this
203 date.

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204 Store all medicines out of the reach of children - preferably in a locked cupboard. Please
205 return left-over medicine to the pharmacist.

206

207 **PRESENTATION OF REQUIP XL:**

208 REQUIP XL 2 mg: [White blister packs \(PVC/PCTFE/PVC blister film backed with white,](#)
209 [hard tempered aluminium foil\)](#) of 28 or 84 tablets [or opaque blister](#)
210 [packs \(PVC/PE/PvdC thermoform blisters and sealed with silver, child-](#)
211 [resistant aluminium lidding foil\)](#) of 28 tablets (2 blisters of 14 tablets).

212 Three week starter pack containing 42 tablets in opaque
213 PVC/PCTFE/PVC blisters.

214 REQUIP XL 4 mg: [White blister packs \(PVC/PCTFE/PVC blister film backed with white,](#)
215 [hard tempered aluminium foil\)](#) of 28 or 84 tablets [or opaque blister](#)
216 [packs \(PVC/PE/PvdC thermoform blisters and sealed with silver, child-](#)
217 [resistant aluminium lidding foil\)](#) of 28 tablets (2 blisters of 14 tablets).

218 REQUIP XL 8 mg: [White blister packs \(PVC/PCTFE/PVC blister film backed with white,](#)
219 [hard tempered aluminium foil\)](#) of 28 or 84 tablets [or opaque blister](#)
220 [packs \(PVC/PE/PvdC thermoform blisters and sealed with silver, child-](#)
221 [resistant aluminium lidding foil\)](#) of 28 tablets (2 blisters of 14 tablets).

222

223 **IDENTIFICATION OF REQUIP XL:**

224 REQUIP XL 2 mg: Pink, film-coated, biconvex capsule-shaped tablet, debossed with 'GS'
225 on one face and '3V2' on the other face.

226 REQUIP XL 4 mg: Light brown (tan), film-coated, biconvex capsule-shaped tablet,
227 debossed with 'GS' on one face and 'WXG' on the other face.

228 REQUIP XL 8 mg: Red, film-coated, biconvex capsule-shaped tablet, debossed with 'GS'
229 on one face and '5CC' on the other face.

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231 **REGISTRATION NUMBER:**

232 REQUIP XL 2 mg: 41/5.4.1/0604

233 REQUIP XL 4 mg: 41/5.4.1/0606

234 REQUIP XL 8 mg: 41/5.4.1/0607

235

236 **NAME AND ADDRESS OF REGISTRATION HOLDER:**

237 GlaxoSmithKline South Africa (Pty) Ltd

238 39 Hawkins Avenue

239 Epping Industria 1

240

241 **DATE OF PUBLICATION:**

242 Last approval: 01 March 2013

243 Date compliant with Regulation 12: 02 February 2016

244

245

246 **History:**

247 Proposed: 15 March 2006 (Inclusion of Prolonged-release tablets for Parkinson's disease)

248 Amended: 10 August 2007 (in-line with CCC recommendations dated 26/04/2007)

249 Amended: 24 January 2008 (in line with CCC recommendations dated 14/12/2007)

250 Amended: 25 March 2008 (new proprietary name proposed for prolonged release tablets – REQUIP XL)

251 Amended: 31 March 2008 (response to CCC recommendations dated 22/02/2008) – compliant pi

252 Amended: 21 April 2009 (In line with GCT versions 17, 19 - 21)

253 Amended: 2 February 2010 (Correction of spelling errors as highlighted in CCC recommendation 13 August

254 2009 for RLS) – Included as Attachment 1

255 Amended: 05 October 2010 (in response to CCC recommendations dated 27/07/2010 – Response D2010-4334)

256 Amended: 28-07-2010 Cape town address details reflected

257 Amended: 04 October 2012 (compliant response to CCC recommendations dated 05/09/2012) Approved: 01

258 March 2013

259 Amended: 30 April 2013 (applicant address to CT, amendment to blister material)

260 **Amended: 02 February 2016 (Implementation of Regulation 9 and 10)**

261

262 **Amended: 06 September 2018 (to bring presentation in line with amended m3.2.P.7, reference to Requip XL 3 mg has been**
 263 **deleted as the license has been cancelled)**

264