

Patient Information Leaflet (clean)

1 **SCHEDULING STATUS: [S3]**

2

3 **SOLIFENACIN 5 GLENMARK** (Film-coated tablets)

4 **SOLIFENACIN 10 GLENMARK** (Film-coated tablets)

5 Solifenacin succinate

6 Contains sugar:

7 **SOLIFENACIN 5 GLENMARK**: 51,25 mg of lactose monohydrate per tablet.

8 **SOLIFENACIN 10 GLENMARK**: 68,33 mg of lactose monohydrate per tablet.

9

10

11 **Read all of this leaflet carefully before you start taking SOLIFENACIN GLENMARK**

- 12
- 13 • Keep this leaflet. You may need to read it again.
 - 14 • If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
 - 15 • **SOLIFENACIN GLENMARK** has been prescribed for you personally and you should
 - 16 not share your medicine with other people. It may harm them, even if their symptoms
 - 17 are the same as yours.

18

19 **What is in this leaflet**

20 1. What **SOLIFENACIN GLENMARK** is and what it is used for

21 2. What you need to know before you take **SOLIFENACIN GLENMARK**

22 3. How to take **SOLIFENACIN GLENMARK**

23 4. Possible side effects

24 5. How to store **SOLIFENACIN GLENMARK**

25 6. Contents of the pack and other information

26

27 1. **What SOLIFENACIN GLENMARK is and what it is used for**

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28 **SOLIFENACIN GLENMARK** belongs to a group of medicines known as anticholinergics. It
29 is used to treat the symptoms of a condition called overactive bladder syndrome, including
30 the following:

- 31 • A frequent need to urinate (usually defined as needing to go more than 8 times in
32 24 hours)
- 33 • Sudden frequent urges to urinate (urinary urgency) and/or
- 34 • Leaking accidents (urinary incontinence or urge incontinence).

35

36 **2. What you need to know before you take SOLIFENACIN GLENMARK**

37 **Do not take SOLIFENACIN GLENMARK:**

- 38 • If you are hypersensitive (allergic) to solifenacin succinate or any of the other
39 ingredients of **SOLIFENACIN GLENMARK** (see *section 6*)
- 40 • If you have an inability to pass water or to empty your bladder completely
- 41 • If you have uncontrolled increased pressure inside of your eyes (uncontrolled narrow
42 angle glaucoma)
- 43 • If you suffer from myasthenia gravis, a muscle disease which can cause extreme
44 weakness of certain muscles, difficulty swallowing, eye weakness and facial expression
45 weakness
- 46 • If you have a severe bowel condition causing your intestines to expand or dilate known
47 as toxic megacolon (a complication associated with ulcerative colitis)
- 48 • If you are undergoing kidney dialysis (a process used to clean your blood when your
49 kidneys are not functioning normally)
- 50 • If you have a severe liver disease
- 51 • If you suffer from a severe kidney disease or a moderate liver disease and you are
52 being treated with medicines that may decrease the removal of **SOLIFENACIN**
53 **GLENMARK** from your body (such as ketoconazole, used to treat fungal infections)
- 54 • If you have fast, irregular heartbeats

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- 56 • If you are pregnant or breastfeeding your baby

57

58 **Warnings and precautions**

59 **Special care should be taken with SOLIFENACIN GLENMARK**

- 60 • If you have trouble emptying your bladder (bladder obstruction) or have difficulty in
61 passing urine (weak urine flow)
- 62 • If you have some obstruction of your digestive system (such as constipation)
- 63 • If you are at risk of your digestive system slowing down (decreased stomach and
64 bowel movements)
- 65 • If you have a condition causing inflammation or ulcers on the lining of your intestines,
66 known as ulcerative colitis (diarrhoea, pain or cramping in your stomach area, loss of
67 body mass or uncomfortable or painful bowel movements)
- 68 • If you suffer from a severe kidney disease
- 69 • If you have a moderate liver disease
- 70 • If you are taking ketoconazole (see **Taking other medicines**
71 **with SOLIFENACIN GLENMARK**)
- 72 • If you are male and you have an enlarged prostate which is causing difficulty to urinate
- 73 • If you have a fever or increased body temperature
- 74 • If you have any other heart condition, or you have to have a heart procedure done,
75 that causes your heart to beat faster than normal
- 76 • If you have had a heart attack
- 77 • If you have high blood pressure
- 78 • If you have Down's syndrome or albinism (absence of pigment in your skin)
- 79 • If you are an elderly person. **SOLIFENACIN GLENMARK** may cause confusion.
- 80 • If you have angioedema (a skin allergy that results in swelling that occurs in the tissue
81 just below the surface of your skin) with difficulty in breathing. Stop **SOLIFENACIN**
82 **GLENMARK** immediately and contact a doctor
- 83

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- 84 • If you have a nervous disorder that is causing bladder problems

85

86 **Other medicines and SOLIFENACIN GLENMARK**

87 Always tell your healthcare provider if you are taking any other medicine.

88 Always tell your healthcare provider if you are using, have recently used or might use any
89 other medicines. (This includes all complementary or traditional medicines.)

90

91 If you are taking any of the following medicines, check with your doctor or pharmacist first
92 before taking **SOLIFENACIN GLENMARK**.

- 93 • Medicines belonging to the same class as **SOLIFENACIN GLENMARK** (anticholinergic
94 medicines) as the effect and side effects of both medicines may be enhanced. An interval
95 of approximately one week should be allowed after stopping treatment with
96 **SOLIFENACIN GLENMARK** before starting other anticholinergic medicines.
- 97 • Medicines belonging to a different class which has the opposite effect of **SOLIFENACIN**
98 **GLENMARK** (cholinergic receptor agonists), as they can reduce the effect of
99 **SOLIFENACIN GLENMARK**.
- 100 • **SOLIFENACIN GLENMARK** can reduce the effect of medicines that stimulate the
101 movement of the digestive tract e.g. metoclopramide (used to treat nausea and vomiting)
102 or cisapride (used to increase the movement of food in your gastrointestinal tract)
- 103 • Medicines that decrease the removal of **SOLIFENACIN GLENMARK** from the body e.g.
104 ketoconazole (used to treat fungal infections)

105

106 **SOLIFENACIN GLENMARK with food and drink**

107 **SOLIFENACIN GLENMARK** can be taken with or without food.

108

109 **Pregnancy, breastfeeding and fertility**

110 *Pregnancy:*

111 Do not use **SOLIFENACIN GLENMARK** if you are pregnant, think that you may be pregnant

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112 or want to become pregnant, as it may harm your unborn baby.

113 If you are pregnant or planning a pregnancy it is very important that you discuss this with your
114 doctor before you receive any treatment. If you get pregnant during your treatment, you must
115 immediately inform your doctor.

116

117 *Breastfeeding:*

118 You must not breastfeed your baby while you are treated with **SOLIFENACIN GLENMARK**
119 because it passes into breast milk and could affect the baby.

120

121 If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or
122 other healthcare professional for advice before you take **SOLIFENACIN GLENMARK**.

123

124 **SOLIFENACIN GLENMARK** contains lactose. If you have been told by your
125 doctor that you have an intolerance to some sugars, contact your doctor before taking this
126 medicinal product.

127

128 **Driving and using machines**

129 **SOLIFENACIN GLENMARK** may cause side effects, such as blurred vision and dizziness
130 and may impair your ability to drive and use machines or perform other skilled tasks. Take
131 special care before performing tasks requiring your attention, until you know how
132 **SOLIFENACIN GLENMARK** will affect you.

133

134 It is not always possible to predict to what extent **SOLIFENACIN GLENMARK** may interfere
135 with your daily activities. You should ensure that you do not engage in the above activities
136 until you are aware of the measure to which **SOLIFENACIN GLENMARK** affects you.

137

138 **3. How to take SOLIFENACIN GLENMARK**

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

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140 Always take **SOLIFENACIN GLENMARK** exactly as your doctor or pharmacist has told you.

141 Check with your doctor or pharmacist if you are not sure.

142

143 The usual dose is 5 mg daily taken with or without food. Your doctor may increase your dose
144 to 10 mg daily.

145 You should swallow the tablet whole with some liquid. Do not crush or chew the tablets.

146

147 **If take more SOLIFENACIN GLENMARK than you should**

148 In the event of an overdose you may experience any of the side effects listed below.

149 • Headache

150 • Dry mouth

151 • Dizziness

152 • Drowsiness

153 • Blurred vision

154 In the event of overdose, consult your doctor or pharmacist. If neither is available, consult
155 the nearest hospital or poison centre.

156

157 **If you forget to take SOLIFENACIN GLENMARK**

158 If you have missed your dose by only a few hours, take the missed
159 dose as soon as you remember. If it is almost time for your next dose, skip the missed dose
160 and take **SOLIFENACIN GLENMARK** at the next regularly scheduled time. Do not take a
161 double dose to make up for the forgotten individual doses.

162

163 **If you stop taking SOLIFENACIN GLENMARK**

164 Do not stop taking **SOLIFENACIN GLENMARK** early, as this might cause the medicine to be
165 ineffective. Your symptoms of overactive bladder may return or worsen. Always consult your
166 doctor if you are considering stopping treatment.

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168 **4. Possible side effects**

169 **SOLIFENACIN GLENMARK** can have side effects.

170 Not all side effects reported for **SOLIFENACIN GLENMARK** are included in this leaflet.

171 Should your general health worsen or if you experience any untoward effects while taking

172 **SOLIFENACIN GLENMARK**, please consult your healthcare provider for advice.

173

174 If any of the following happens, stop taking **SOLIFENACIN GLENMARK** and tell your doctor
175 immediately or go to the casualty department at your nearest hospital:

- 176
- 177 • A severe, potentially life-threatening allergic reaction (anaphylaxis) which can present
178 as swelling of the face and throat area, skin rash, nausea, vomiting, difficulty
breathing and shock

179 These are all very serious side effects. If you have them, you may have had a serious reaction
180 to **SOLIFENACIN GLENMARK**. You may need urgent medical attention or hospitalisation.

181

182 Tell your doctor immediately or go to the casualty department at your nearest hospital if you
183 notice the following:

- 184
- 185 • Erythema Multiforme (a skin reaction that can be triggered by an infection or some
medicines)

186 These are all serious side effects. You may need urgent medical attention.

187

188 Tell your doctor if you notice any of the following:

189 Frequent side effects:

- 190
- 191 • Blurred vision (loss of sharpness of eyesight)
 - 192 • Dry mouth
 - 193 • Constipation (Passing less than three bowel movements a week or has difficult
194 bowel movements)
 - 195 • Nausea (a queasy sensation including an urge to vomit)
 - Dyspepsia (upper abdominal discomfort such as a burning sensation, bloating or

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196 gassiness, nausea or feeling full too quickly after starting to eat)

197 • Abdominal pain (stomach pain)

198

199 Less frequent side effects:

200 • Urinary tract infection (an infection in any part of the urinary system, the kidneys,
201 bladder or urethra)

202 • Cystitis (inflammation of the bladder)

203 • Hallucinations (seeing or hearing things that are not real)

204 • Confusional state (serious disturbance in mental abilities that results in confused
205 thinking and reduced awareness of surroundings)

206 • Somnolence (sleepiness, drowsiness)

207 • Dysgeusia (altered perception of taste)

208 • Dizziness (altered sense of balance and place, possibly described as lightheaded,
209 feeling faint or as if head is spinning)

210 • Headache (a painful sensation in any part of the head, ranging from sharp to dull)

211 • Nasal dryness

212 • Gastro-oesophageal reflux diseases

213 • Dry throat

214 • Obstruction of your colon

215 • Faecal impaction (hardened stool that's stuck in the rectum or lower colon due to
216 chronic constipation)

217 • Dry skin

218 • Pruritus (an uncomfortable, irritating sensation that creates an urge to scratch that
219 can involve any part of the body)

220 • Rash (widespread eruptions or skin lesions)

221 • Urticaria (a raised, itchy rash that appears on the skin)

222

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- 224 • Angioedema (swelling underneath the skin) (painless swelling under the skin,
225 triggered by an allergy)
- 226 • Difficulty in micturition (difficulty urinating can be a result of anatomical abnormalities
227 within the genitourinary tract)
- 228 • Urinary retention (difficulty urinating and completely emptying the bladder)
- 229 • Fatigue (overall tiredness or lack of energy)
- 230 • Peripheral oedema (swelling of your lower legs or hands)

231

232 Side effects with unknown frequency:

- 233 • Decreased appetite
- 234 • Hyperkalaemia (high level potassium in the blood)
- 235 • Delirium (serious disturbance in mental abilities that results in confused thinking and
236 reduced awareness of surroundings)
- 237 • Glaucoma (a group of eye disorders causing blindness)
- 238 • Torsade de Pointes (disturbance of the heart's rhythm)
- 239 • Electrocardiogram QT prolonged
- 240 • Dysphonia (disorders of the voice)
- 241 • Ileus (a temporary lack of the normal muscle contractions of the intestines)
- 242 • Abdominal discomfort
- 243 • Liver disorder, liver function test abnormal
- 244 • Exfoliative dermatitis (a severe skin condition that causes extreme shedding of the
245 top layers of your skin)
- 246 • Muscle weakness
- 247 • Renal impairment (kidney failure or damage)

248 If you notice any side effects not mentioned in this leaflet, please inform your doctor or
249 pharmacist.

250

251 **Reporting of side effects**

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252 If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side
253 effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under
254 SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>.

255 By reporting side effects, you can help provide more information on the safety of
256 **SOLIFENACIN GLENMARK.**

257

258 **5. How to store SOLIFENACIN GLENMARK**

259 Store all medicines out of reach of children.

260 Store at or below 25 °C.

261 Store in the outer container until required for use.

262

263 Return all unused medicine to your pharmacist.

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

265

266 **6. Contents of the pack and other information**

267 **What SOLIFENACIN GLENMARK contains**

268 The active ingredient is solifenacin succinate.

269 **SOLIFENACIN 5 GLENMARK:** Each film-coated tablet contains 5 mg solifenacin succinate.

270 **SOLIFENACIN 10 GLENMARK:** Each film-coated tablet contains 10 mg solifenacin
271 succinate.

272 The other ingredients are corn starch, hypromellose, isopropyl alcohol, lactose monohydrate,
273 magnesium stearate, methylene chloride.

274 Coating:

275 Instacoat Universal A05G32262, Instacoat Universal A05G32262, purified water.

276

277 **What SOLIFENACIN GLENMARK looks like and contents of the pack**

278 **SOLIFENACIN 5 GLENMARK:** Round, biconvex, yellow, film coated tablet debossed with
279 “G” on one side and “71” on the other side.

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280 **SOLIFENACIN 10 GLENMARK:** Round, biconvex, pink, film coated tablet debossed with

281 "G" on one side and "52" on the other side.

282

283 Multilayer aluminium foil with a blue to greenish inner layer/ aluminium layer blister strip,

284 containing 8 tablets each, packed in an outer carton.

285 Pack sizes: 30 tablets (10 tablets per blister strip and 3 blister strips in each pack) OR

286 100 tablets (10 tablets per blister strip and 10 blister strips in each pack).

287

288 **Holder of Certificate of Registration**

289 **Glenmark Pharmaceuticals South Africa (Pty) Ltd**

290 34 Monte Carlo Crescent,

291 Block A, First floor,

292 Kyalami Park, Midrand,

293 1684

294

295 **This leaflet was last revised in**

296 17 September 2024

297

298 **Registration number**

299 **SOLIFENACIN 5 mg GLENMARK:** 54/5.4/0066.064

300 **SOLIFENACIN 10 mg GLENMARK:** 54/5.4/0067.065

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302