

1 **PATIENT INFORMATION LEAFLET**

2 **SCHEDULING STATUS:** **S5**

3

4 **PROPRIETARY NAME AND DOSAGE FORM:**

5 MOLIPAXIN 50 mg Capsules

6 MOLIPAXIN 100 mg Capsules

7

8 **Read all of this leaflet carefully before you start taking MOLIPAXIN:**

- 9
- 10 ▪ Keep this leaflet. You may need to read it again.
  - 11 ▪ If you have further questions, please ask your doctor or your pharmacist.
  - 12 ▪ MOLIPAXIN has been prescribed for you personally and you should not share your medicine  
13 with other people. It may harm them, even if their symptoms are the same as yours.

13

14 **WHAT MOLIPAXIN CONTAINS:**

15 Each Molipaxin 50 mg Capsule contains 50 mg of the active substance, trazodone hydrochloride.

16 Each Molipaxin 100 mg Capsule contains 100 mg of the active substance, trazodone  
17 hydrochloride.

18 Other ingredients include lactose monohydrate, magnesium stearate, gelatin, erythrosine E127,  
19 indigo carmine E132, titanium dioxide E171, yellow iron oxide E172 and ink 0619 (S-1-20952).

20 The 100 mg Molipaxin Capsules also contain Red Iron Oxide (E172).

21 Contains sugar (lactose).

22

23 **WHAT MOLIPAXIN IS USED FOR:**

24 Molipaxin belongs to a group of medicines called antidepressants. It is used to treat depression  
25 and depression associated with anxiety.

26

27 **BEFORE TAKING MOLIPAXIN:**

28 **Do not take MOLIPAXIN:**

- 29 • if you are hypersensitive (allergic) to trazodone hydrochloride, or any of the other ingredients  
30 of MOLIPAXIN (see WHAT MOLIPAXIN CONTAINS). Signs of an allergic reaction can  
31 include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- 32 • if you are taking any other psychotropic medicines of which you have not informed your  
33 doctor
- 34 • if you are taking a monoamine oxidase inhibitor (MAOI) or if you have taken them in the last 2  
35 weeks. You should not receive MAOIs within one week of stopping MOLIPAXIN
- 36 • if you have recently had a heart attack
- 37 • if you are a heavy drinker or are taking sleeping tablets.

38

39 **Take special care with MOLIPAXIN:**

40 Molipaxin **should not** be given to children and teenagers under 18 years of age.

41

42 If any of the following applies to you, you must tell your doctor or healthcare professional before  
43 taking MOLIPAXIN:

- 44 • if you are pregnant or trying to become pregnant
- 45 • if you are breastfeeding
- 46 • if you have epilepsy, since gradual changes to your MOLIPAXIN dose may be required
- 47 • if you have liver or kidney disease
- 48 • if you have heart disease or taking any medicines for irregular heartbeats (see Taking other  
49 medicines with MOLIPAXIN)

- 50 • if you are elderly, since you may be more prone to side effects like feeling faint when you  
51 stand up quickly (see POSSIBLE SIDE EFFECTS). If you are taking medicines for high blood  
52 pressure the dose may need to be lowered

53

54 If any of the following applies to you, you must tell your doctor or health care provider  
55 immediately:

- 56 • if you notice any of the following symptoms: nausea (feeling sick), vomiting (being sick),  
57 stomach pain or yellowing of the skin and the white areas of your eyes while taking  
58 MOLIPAXIN. These may be signs of a serious liver disorder that require stopping of  
59 MOLIPAXIN treatment
- 60 • if you have flu-like symptoms such as a sore throat and fever or any blood disorder. It may be  
61 necessary to stop MOLIPAXIN treatment
- 62 • if you have schizophrenia or other type of mental disorder and your symptoms get worse.
- 63 • if you take other medicines for depression and experience high fever and muscle stiffness  
64 (see Taking other medicines with MOLIPAXIN)
- 65 • You develop the less frequent, but serious side effect of inappropriate or prolonged penile  
66 erections (See POSSIBLE SIDE EFFECTS). Stop taking MOLIPAXIN immediately and go to  
67 your doctor for treatment.

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71 **Thoughts of suicide and worsening of your depression or anxiety disorder:**

72 If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming  
73 or killing yourself. These may be increased when first starting Molipaxin, since Molipaxin takes

74 time to work. The beneficial effects normally start to become evident after two weeks, but this  
75 may take several weeks.

76 You may be more likely to experience self-injurious or suicidal thoughts:

- 77 ▪ if you have previously had thoughts about killing or harming yourself
- 78 ▪ if you are a young adult. Information from clinical trials has shown an increased risk of suicidal  
79 behaviour in adults aged less than 25 years with psychiatric conditions who were treated with  
80 an antidepressant such as MOLIPAXIN.

81

82 If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a  
83 hospital straight away.

84

85 You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety  
86 disorder, and ask them to read this leaflet. You might ask them to tell you if they think your  
87 depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

88

89 If any of the following applies to you, tell your doctor, who may decide to do additional monitoring:

- 90 • you have an overactive thyroid gland (hyperthyroidism)
- 91 • you have problems passing water or need to pass water (urine) frequentl.
- 92 • you have narrow angle glaucoma (an eye disorder)
- 93 • you are going to have an anaesthetic (for an operation), tell your doctor or dentist that you are  
94 taking MOLIPAXIN.

95

96 **Taking MOLIPAXIN with food and drink:**

97 It is best to avoid alcohol while taking MOLIPAXIN. Your capsules may be taken after meals or at  
98 bed time, depending on how your doctor prescribed your capsules.

99

100 **Pregnancy and Breastfeeding:**

101 There is currently no information about the use of MOLIPAXIN during pregnancy or  
102 breastfeeding. Therefore you should not use MOLIPAXIN if you are pregnant. You should not  
103 breastfeed your baby if you are taking MOLIPAXIN.

104

105 Talk to your doctor or health care professional before taking MOLIPAXIN if you are pregnant,  
106 might become pregnant, or think you may be pregnant. If you are breastfeeding or planning to  
107 breastfeed, talk to your doctor or pharmacist before taking any MOLIPAXIN.

108

109 **Driving and using machinery:**

110 MOLIPAXIN may make you feel sleepy, dizzy or confused and may cause blurry vision. Care  
111 must be taken when driving or operating machinery.

112

113 **Important information about some of the ingredients of MOLIPAXIN:**

114 MOLIPAXIN capsules contain lactose which may have an effect on the control of your blood  
115 sugar if you have diabetes mellitus. Patients with the rare hereditary conditions of  
116 lactose/fructose or galactose intolerance should not take MOLIPAXIN.

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118

119 **Taking other medicines with MOLIPAXIN:**

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

122

123 Some other medicines and MOLIPAXIN may interfere with each other, such as:

- 124 • muscle relaxants and inhaled anaesthetics
- 125 • medicines that contains alcohol
- 126 • monoamine oxidase inhibitors (MAOIs). Tell your doctor if you are taking a monoamine
- 127 oxidase inhibitor (MAOI) or if you have taken them in the last 2 weeks (see Do not take
- 128 MOLIPAXIN)
- 129 • other anti-depressants such as amitriptyline or fluoxetine
- 130 • sedatives (such as tranquilizers and sleeping pills)
- 131 • digoxin (used to treat heart problems)
- 132 • warfarin (used to stop your blood from clotting)
- 133 • medicines used to treat epilepsy such as carbamazepine and phenytoin
- 134 • medicines used to treat high blood pressure such as clonidine
- 135 • medicines used to treat heart disease such as digoxin or amiodarone
- 136 • antibiotics such as erythromycin
- 137 • antiretrovirals (for HIV) such as ritonavir and indinavir
- 138 • antifungal medicines such as ketoconazole and itraconazole
- 139 • levodopa (used to treat Parkinson's disease)
- 140 • St. John's Wort (a herbal remedy).

141

142 Your doctor or pharmacist has more information on medicines to be careful with or to avoid while  
143 taking MOLIPAXIN, as the list above may not be complete.

144

#### 145 **HOW TO TAKE MOLIPAXIN:**

146 **Do not share MOLIPAXIN prescribed for you with any other people.** It may harm them, even  
147 if their symptoms are the same as yours.

148

149 **How much to take:**

150 Always take the number of capsules your doctor has told you to take. You should check with your  
151 doctor or pharmacist if you are unsure.

152

153 **Depression:**

154 You will usually start by taking 150 mg a day, by mouth. Elderly or frail people may need to start  
155 with a lower dose of 100 mg a day.

156 Your doctor may later decide to increase your daily dose. The usual dose is between 300 – 400  
157 mg each day, depending on your condition. For adults in hospital the dose may be as high as  
158 600 mg each day.

159 Make sure that you know how many capsules your doctor has prescribed and do not take any  
160 more than this.

161 Your doctor may want you to take your capsules either in divided doses after food, or as a single  
162 dose as you go to bed.

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166 **Mixed Anxiety and Depression:**

167 The starting dose is normally 100 mg to 150 mg a day. When depression is the predominant  
168 symptom the dose may be 300 mg to 400 mg. Carefully follow the instructions of your doctor.

169

170 MOLIPAXIN **should not** be given to children and teenagers under 18 years of age.

171

172 **If you take more MOLIPAXIN than you should:**

173 If you have taken more capsules than you should, **contact your doctor or pharmacist**  
174 **immediately. If neither is available, immediately contact the nearest hospital or poison**  
175 **control centre.** Do this even if there are no signs of discomfort or poisoning. You may need  
176 urgent medical attention.

177 Take the medicine pack with you. This is so the doctor knows what you have taken.

178

179 **If you forget to take MOLIPAXIN:**

180 If you forget a dose, take it as soon as possible when you remember. Do not take extra capsules  
181 to make up for the missed dose.

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184 **Effects when treatment with MOLIPAXIN is stopped:**

185 You should take MOLIPAXIN for as long as your doctor has told you. Do not stop taking your  
186 capsules without your doctor knowing, even if you feel better. The capsules may need to be taken  
187 for a number of weeks or months. When your doctor tells you to stop taking MOLIPAXIN, it is  
188 better to do so gradually to minimise symptoms such as feeling sick, headache and not feeling  
189 well.

190

191 **POSSIBLE SIDE EFFECTS:**

192 MOLIPAXIN can have side effects:

193 ***If you experience any of the following side effects, stop taking MOLIPAXIN and tell your***  
194 ***doctor immediately or go to the casualty department at your nearest hospital:***

195 *Frequency unknown:*

- 196 • you get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty  
197 swallowing or breathing, itching of the skin and nettle rash. This may mean you are  
198 having an allergic reaction to MOLIPAXIN
- 199 • fits or seizures
- 200 • a combination of high temperature (fever), sweating, stiff muscles, feeling very drowsy or  
201 faint, large increase in blood pressure or heartbeat (a disorder called “Neuroleptic  
202 Malignant Syndrome”)
- 203 • yellowing of the skin or eyes, This could be a serious liver problem (such as jaundice) that  
204 could lead to liver failure with potentially fatal outcome
- 205 • you have severe abdominal pain and bloating, are being sick (vomiting) and have  
206 constipation. These may be signs that your intestine is not working properly (paralytic  
207 ileus).

208 *Less frequent:*

- 209 • getting infections more easily than usual. This could be because of a blood disorder  
210 (agranulocytosis)
- 211 • bruising more easily than usual. This could be because of a blood disorder  
212 (thrombocytopenia)
- 213 • painful erection of the penis, unrelated to sexual activity, that will not go away (priapism).

214 These are all very serious side effects. If you have them, you may need urgent medical attention  
215 or hospitalisation.

216

217 ***Tell your doctor immediately or go to the casualty department at your nearest hospital if***  
218 ***you notice any of the following:***

219 *Less frequent:*

- 220 • rapid, slow or irregular heartbeat.

221 *Frequency unknown:*

- 222 • feeling tired, faint, dizzy, having pale skin. These could be signs of anaemia
- 223 • feeling confused, restless, sweating, shaking, shivering, hallucinations (strange visions or
- 224 sounds), sudden jerks of the muscles or a fast heartbeat, you may have something called
- 225 Serotonin syndrome
- 226 • feeling very unwell possibly with shortness of breath (dyspnoea), difficulty in walking or
- 227 walking with a shuffling gait, shaking, uncontrolled muscle twitching, and a high temperature
- 228 (above 38 °C). This could be a rare condition known as “Neuroleptic Malignant Syndrome”
- 229 • having thoughts of harming or killing yourself
- 230 • unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin
- 231 (paraesthesia).

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

233

234 **Tell your doctor if you notice any of the following:**

235 *Frequent:*

- 236 • drowsiness
- 237 • headache, dizziness, confusion, shaking (tremor), excitement
- 238 • nausea (feeling sick), vomiting, dry mouth.

239 *Less frequent:*

- 240 • constipation or diarrhoea
- 241 • weakness
- 242 • blurred vision
- 243 • skin rashes

244 • feeling dizzy or light-headed on standing or sitting up quickly (orthostatic hypotension).

245 *Frequency unknown:*

246 • feeling less alert, irritability or agitation, restlessness or difficulty sleeping (insomnia)

247 • altered taste

248 • weight loss

249 • indigestion, increased amounts of saliva,

250 • unexpected swelling (fluid retention), chest pain

251 • fainting (syncope)

252 • blocked nose

253 • itching, sweating more than usual

254 • pain in limbs, back pain, pain in your muscles, pain in your joints

255 • jerking movements that you cannot control, mainly in the arms and legs, uncontrolled muscle  
256 movements or twitches, difficulty with speaking

257 • frequent infections with high temperature, severe chills, sore throat or mouth ulcers. These  
258 could be signs of a blood problem called leucopenia.

259 • feeling anxious or more nervous than usual, feeling agitated

260 • overactive behaviour or thoughts (mania), believing things that are not true (delusions),  
261 memory disturbance

262 • nightmares

263 • decreased sex drive

264 • high blood pressure

265 • flu type symptoms, high temperature

266 • higher than normal number of white blood cells or liver enzymes (shown by a blood test)

267 • feeling tired, weak and confused, having muscle that ache, are stiff or do not work well.

268 There may also be headache, loss of appetite, nausea or vomiting, convulsion. This may be  
269 due to low sodium levels in your blood.

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271 Not all side effects reported for MOLIPAXIN are included in this leaflet. Should your general  
272 health worsen or if you experience any untoward effects while taking MOLIPAXIN, please consult  
273 your doctor, pharmacist or other healthcare professional for advice.

274

275 **STORAGE AND DISPOSING OF MOLIPAXIN:**

276 **Store all medicines out of reach of children.**

277 Store in a cool, dry place at or below 30 °C and protect from light. Keep blister in carton until  
278 required for use.

279 Do not use MOLIPAXIN after the expiry date stated on the blisters and outer carton. The expiry  
280 date refers to the last day of that month.

281 Return all unused medicine to your pharmacist. Medicines should not be disposed of via  
282 wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer  
283 required. These measures will help to protect the environment.

284

285 **PRESENTATION OF MOLIPAXIN:**

286 MOLIPAXIN capsules (all strengths) are presented in clear PVDC coated PVC/Aluminium blister  
287 packs each containing 20 capsules. The 50 mg and 100 mg capsules are packed in cartons of  
288 100 capsules.

289

290 **IDENTIFICATION OF MOLIPAXIN:**

291 **MOLIPAXIN 50 mg Capsules:** opaque, violet cap and opaque, green body with R365B printed  
292 on one half and the company logo on the other half, containing a white powder.

293 **MOLIPAXIN 100 mg Capsules:** opaque, violet cap and opaque, fawn body with R365C printed  
294 on one half and the company logo on the other half, containing a white powder.

295

296 **REGISTRATION NUMBER:**

297 MOLIPAXIN 50 mg capsules: E/1.2/9

298 MOLIPAXIN 100 mg capsules: E/1.2/10

299

300 **NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF**  
301 **REGISTRATION:**

302 sanofi-aventis south africa (pty) ltd

303 2 Bond Street

304 Midrand, 1685

305 South Africa

306

307

308 **DATE OF PUBLICATION:**

309 Date registered: 27 April 1981

310 Date revised: 05 February 2019 (SR-PIN)