

PROPOSED PATIENT INFORMATION LEAFLET

- 1 Read all of this leaflet carefully before you start taking SOLIAN.
- 2 • Keep this leaflet. You may need to read it again.
- 3 • If you have any questions, ask your doctor or pharmacist.
- 4 • SOLIAN has been prescribed for you. Do not pass it on to others. It may harm them,
5 even if their symptoms are the same as yours.

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7 **SCHEDULING STATUS:**

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9 **PROPRIETARY NAME** (and dosage form)

10 **SOLIAN 50 mg** Tablet

11 **SOLIAN 200 mg** Tablet

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13 **WHAT SOLIAN 50 mg and SOLIAN 200 mg CONTAINS:**

14 Each SOLIAN 50 mg tablet contains 50 mg of the active ingredient, amisulpride.

15 Each SOLIAN 200 mg tablet contains 200 mg of the active ingredient amisulpride.

16 SOLIAN 50 mg and SOLIAN 200 mg also contains hypromellose, lactose monohydrate,
17 magnesium stearate, microcrystalline cellulose and sodium starch glycolate.

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19 **WHAT SOLIAN IS USED FOR:**

20 SOLIAN is used in the treatment of acute and chronic schizophrenia.

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24 **BEFORE YOU TAKE SOLIAN:**

25 **Do not take SOLIAN if:**

- 26 • you have an allergic reaction to amisulpride or any of the ingredients listed above.

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- 27 • you are pregnant, likely to become pregnant, or are breastfeeding (see “Pregnancy and
28 Breastfeeding”).
- 29 • you have a prolactin dependent tumour (tumor of the pituitary gland) or breast cancer.
- 30 • you have phaeochromocytoma (a tumour on the adrenal gland.)
- 31 • you have serious kidney problems.
- 32 • you are a child under 15 years of age.
- 33 • you are using medicines that could induce or enhance the risk of torsades de pointes
34 (serious cardiac rhythm disorders) or prolong the QT-interval such as quinidine,
35 disopyramide, amiodarone, sotalol.
- 36 • you have a congenital QT-interval prolongation.

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38 **Take special care with SOLIAN in the following cases:**

- 39 • In the event of onset of muscular rigidity, consciousness disorders accompanied by
40 unexplained fever during treatment, stop taking SOLIAN immediately and contact the
41 doctor.

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46 **You should inform your doctor before you take SOLIAN if you have any of the** 47 **following:**

- 48 • Prolongation of the QT-interval.
- 49 • Parkinson’s disease - A slowly progressive neurologic disease characterized by a fixed
50 inexpressive face, a tremor at rest, slowing of voluntary movements, a gait with short
51 accelerating steps. SOLIAN may worsen your symptoms.
- 52 • A history of epileptic seizures.

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- 53 • Diabetes mellitus. Monitor glucose levels carefully during treatment.
- 54 • Stroke.
- 55 • Risk or history of venous thromboembolism. SOLIAN has been associated with formation
- 56 of blood clots.
- 57 • If you are elderly and suffer from dementia.

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59 **Pregnancy and Breastfeeding:**

60 Safety in pregnancy has not been established (See “Do not take SOLIAN if”). If you use

61 SOLIAN during pregnancy, your newborn baby may be adversely affected.

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63 **Driving and using machinery:**

64 SOLIAN may affect your reaction times so you should not drive vehicles or operate machinery

65 while you are taking it, until you are sure that you are not affected.

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69 **Important information about some of the ingredients of SOLIAN:**

70 SOLIAN contains lactose, which is a type of sugar. If you have been told by your doctor that

71 you have an intolerance to some sugars, contact your doctor before taking SOLIAN.

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73 **Taking other medicines with SOLIAN:**

74 If you are taking medication on a regular basis, including complementary or traditional

75 medicines, the use of SOLIAN with these medicines may cause undesirable interactions.

76 Please consult your doctor, pharmacist or other health care professional for advice.

77 You should not drink alcohol while you are taking SOLIAN.

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79 SOLIAN can interact with some other medicines. These are:

- 80 • Central Nervous System depressants (medicines which act on the brain) including
81 narcotics (used for relieving severe pain), anaesthetics, analgesics, sedative H₁
82 antihistamines (which cause drowsiness), barbiturates and benzodiazepines (sleeping
83 tablets) and medicines used to treat anxiety, clonidine and its derivatives.
- 84 • Medicines which lower blood pressure and medicines which increase blood pressure.
- 85 • Dopamine agonists (e.g. levodopa used in Parkinson's disease) since SOLIAN may
86 interfere with their action.
- 87 • Medicines, which could induce torsades de pointes (serious cardiac rhythm disorders).
 - 88 ○ Class Ia antidysrhythmic agents such as quinidine, disopyramide.
 - 89 ○ Class III antidysrhythmic agents such as amiodarone, sotalol.
 - 90 ○ Other medications such as bepridil, cisapride, sultopride, thioridazine, methadone, IV
91 erythromycin, IV vincamine, halofantrine, pentamidine, sparfloxacin.
- 92 • Medicines, which enhance the risk of torsades de pointes (serious cardiac rhythm
93 disorders) or could prolong the QT intervals.
 - 94 ○ Bradycardia-inducing medications such as beta-blockers, bradycardia-inducing
95 calcium channel blockers such as diltiazem and verapamil, clonidine, guanfacine;
96 digoxin.
 - 97 ○ Medications, which induce hypokalaemia: hypokalaemic diuretics, stimulant laxatives,
98 IV amphotericin B, glucocorticoids, tetracosactides. Hypokalaemia should be
99 corrected.
 - 100 ○ Neuroleptics such as pimozide, haloperidol; imipramine antidepressants; lithium.

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102 **HOW TO TAKE SOLIAN**

103 **Do not share medicine prescribed for you with any other person.**

104 **Dosage and Directions for use:**

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105 Doses are adjusted individually and can range from 50 mg (one tablet of SOLIAN 50 mg) up
106 to 800 mg (four tablets of SOLIAN 200 mg) per day. This will depend on the nature and
107 intensity of your illness and you should follow your doctor's instructions carefully.

108 If you are taking up to 400 mg SOLIAN a day, you should take it in one dose. If you are taking
109 more than 400 mg SOLIAN a day you should divide the dose into two and take half in the
110 morning and half in the evening.

111 If you are in any doubt ask your doctor or pharmacist.

112 You should swallow your tablets with plenty of water.

113 Some types of meal may affect how quickly SOLIAN tablets start to work. If possible, it is
114 preferable to take SOLIAN before a meal and at about the same time(s) each day.

115 Do not stop taking SOLIAN just because you feel better. It is important to keep taking the
116 tablets until your doctor tells you to stop.

117 **DO NOT TAKE MORE THAN THE DOSAGE RECOMMENDED BY YOUR DOCTOR.**

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119 **If you take more SOLIAN than you should:**

120 In the event of an over dosage, consult your doctor or pharmacist. If neither is available,
121 contact the nearest hospital or poison control centre and tell them how many tablets have
122 been taken.

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124 **If you forget to take SOLIAN:**

125 Take the following dose as usual. Do not double the dose. If you have forgotten several
126 doses, consult your doctor.

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128 **POSSIBLE SIDE EFFECTS:**

129 SOLIAN can have side effects. Particularly:

130 • sleeplessness, anxiety, restlessness

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- 131 • sleepiness
- 132 • gastrointestinal disorders (constipation, nausea, vomiting, dry mouth)
- 133 • weight gain
- 134 • absence of menstrual periods, abnormal secretion of breast milk in women, swelling of
- 135 breasts in men; difficulty reaching orgasm, impotence
- 136 • low blood pressure (causing dizziness), slowing of the heartbeat, QT-prolongation and
- 137 cardiac rhythm disorders
- 138 • allergic reactions
- 139 • increase in liver enzymes, particularly transaminases
- 140 • torticollis, abnormal movement of certain eye muscles; intense contraction of jaws and
- 141 involuntary movements.
- 142 • convulsions
- 143 • increased glucose levels.
- 144
- 145 Sometimes trembling, pronounced muscle stiffness or spasm, slowness of movement, excess
- 146 saliva or restlessness can occur but this will usually be reduced if your dose of SOLIAN is
- 147 lowered by your doctor or if your doctor prescribes you an additional medicine.
- 148
- 149 SOLIAN could cause uncontrollable movements, mainly of the face or tongue. Should this
- 150 occur, talk to your doctor.
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- 152 If you get an unexplained high temperature (combined with faster breathing, sweating,
- 153 muscle stiffness and reduced consciousness) while taking SOLIAN you should stop the
- 154 tablets and tell your doctor straight away.
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156 Not all side effects reported for this medicine are included in this leaflet. Talk to your doctor if
157 you notice any other side effects not mentioned in this leaflet or a change in your general
158 health whilst taking SOLIAN.

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160 **STORING AND DISPOSING OF SOLIAN:**

161 Keep out of the reach and sight of children.

162 It should be stored in a dry place at or below 25 °C in its original container.

163 Do not take this medicine after the expiry date shown on the carton and blister:

164 Medicines should not be disposed of via wastewater or household waste. Ask your
165 pharmacist how to dispose of medicines no longer required.

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167 **PRESENTATION OF SOLIAN:**

168 **SOLIAN 50 mg** is available in blister packs of 10 packed in cartons of 30 and 150.

169 **SOLIAN 200 mg** is available in blister packs of 10 packed in cartons of 30 and 150.

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171 **IDENTIFICATION OF SOLIAN:**

172 SOLIAN 50 mg: White to off-white, round, flat faced tablet, weighing approximately 120 mg
173 engraved 'AMI 50' on one face

174 SOLIAN 200 mg: White to off-white, round, flat faced tablet, weighing approximately 480 mg
175 engraved 'AMI 200' on one face and with a breakable bar on the other face.

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177 **REGISTRATION NUMBERS:**

178 **SOLIAN 50 mg:** 34/2.6.5/0116

179 **SOLIAN 200 mg:** 34/2.6.5/0117

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181 **NAME AND ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:**

182 sanofi-aventis south africa (pty) ltd

183 2 Bond Street

184 Midrand

185 1685

186 South Africa

187

188 **DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:**

189 25 October 2012

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