

**CLEAN PROPOSED PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS:** S5

**ATOXTRIN 10 mg** Hard Gelatine Capsules

**ATOXTRIN 18 mg** Hard Gelatine Capsules

**ATOXTRIN 25 mg** Hard Gelatine Capsules

**ATOXTRIN 40 mg** Hard Gelatine Capsules

**ATOXTRIN 60 mg** Hard Gelatine Capsules

**ATOXTRIN 80 mg** Hard Gelatine Capsules

**Atomoxetine hydrochloride**

Sugar free

**WARNING:**

**SUICIDAL IDEATION IN CHILDREN AND ADOLESCENTS**

**ATOXTRIN (atomoxetine) increased the risk of suicidal ideation in short-term studies in children or adolescents with Attention-Deficit/Hyperactivity Disorder (AHDH). Anyone considering the use of ATOXTRIN in a child or adolescent must balance this risk with the clinical need. Co-morbidities occurring with ADHD may be associated with an increase in the risk of suicidal ideation and/or behaviour. Patients who are started on therapy should be monitored closely for suicidality (suicidal thinking and behaviour), clinical worsening, or unusual changes in behaviour. Families and caregivers should be advised of the need for close observation and communication with the prescriber. ATOXTRIN is approved for ADHD in paediatric and adult patients. ATOXTRIN is not approved for major depressive disorder.**

26.

**Read all of this leaflet carefully before you start taking ATOXTRIN**

27.

- Keep this leaflet. You may need to read it again.

28.

- If you have further questions, please ask your doctor or your pharmacist.

29.

- ATOXTRIN 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.

30.

31.

32.

33.

**What is in this leaflet**

34.

**1. What ATOXTRIN is and what it is used for**

35.

**2. What you need to know before you take ATOXTRIN**

36.

**3. How to take ATOXTRIN**

37.

**4. Possible side effects**

38.

**5. How to store ATOXTRIN**

39.

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

40.

41.

**1. What ATOXTRIN is and what it is used for**

42.

**What it is used for**

43.

ATOXTRIN contains atomoxetine and is used to treat attention-deficit and hyperactivity disorder (ADHD). It is used:

44.

45.

- in children over six years of age

46.

- in adolescents

47.

- in adults

48.

49.

It is used only as a part of the total treatment of the disease which also requires treatments which do not involve medicines, such as counselling and behavioural therapy.

50.

51.

52.

53. It is not for use as a treatment for ADHD in children under 6 years of age as it is not  
54. known if the medicine works or is safe in these people.

55.

56. In adults, this medicine is used to treat ADHD when the symptoms are very  
57. troublesome and affect your work or social life and when you have had symptoms of  
58. the disease as a child.

59.

60. **How it works**

61. This medicine increases the amount of noradrenaline in the brain. This is a chemical  
62. that is produced naturally and increases attention and decreases impulsiveness and  
63. hyperactivity in patients with ADHD. This medicine has been prescribed to help  
64. control the symptoms of ADHD. This medicine is not a stimulant and is therefore not  
65. addictive. It may take a few weeks after you start the medicine for your symptoms to  
66. fully improve.

67.

68. **About ADHD**

69. Children and adolescents with ADHD find it:

70. - hard to sit still  
71. - hard to concentrate

72.

73. It is not their fault that they cannot do these things. Many children and adolescents  
74. struggle to do these things. However, with ADHD this can cause problems with  
75. everyday life. Children and adolescents with ADHD may have difficulty learning and  
76. doing homework. They find it hard to behave well at home, at school or in other  
77. places. ADHD does not affect the intelligence of a child or adolescent.

78.

79. Adults with ADHD find it difficult to do all the things that children find difficult; however,  
80. this may mean they have problems with:

81. - work

82. - relationships

83. - low self esteem

84. - education

85.

86. **2. What you need to know before you take ATOXTRIN**

87. **Do not take ATOXTRIN if you:**

88. - are allergic to atomoxetine or any of the other ingredients of this medicine.

89. - took a medicine known as a monoamine oxidase inhibitor (MAOI), for example  
90. phenelzine or linezolid (an antibiotic used to treat certain serious bacterial  
91. infections), in the last two weeks. An MAOI is sometimes used for depression and  
92. other mental-health problems; taking ATOXTRIN with an MAOI could cause  
93. serious side effects or be life-threatening. You also need to wait at least 14 days  
94. after you stop taking this medicine before you take an MAOI.

95. - have an eye disease called narrow-angle glaucoma (increased pressure in your  
96. eye).

97. - have serious problems with your heart which may be affected by an increase in  
98. heart rate and/or blood pressure, as this may be an effect of ATOXTRIN.

99. - have serious problems with the blood vessels in your brain - such as a stroke,  
100. swelling and weakening of part of a blood vessel (aneurysm) or narrow or blocked  
101. blood vessels.

102. - have a tumour of your adrenal gland (phaeochromocytoma).

103. - have uncontrolled high blood pressure or impairment of your liver function.

104.

105. Do not take ATOXTRIN if any of the above applies to you. If you are not sure, talk to  
106. your doctor or pharmacist before you take this medicine. This is because this  
107. medicine can make these problems worse.

108.

109. **Warnings and precautions**

110. Both adult and children should be aware of the following warnings and precautions.

111. Talk to your doctor or pharmacist before taking ATOXTRIN if you have:

112. - thoughts about killing yourself or trying to kill yourself, hostility (predominantly  
113. aggression, oppositional behaviour and anger) and emotional lability (rapid, often  
114. exaggerated changes in mood, where strong emotions or feelings (uncontrollable  
115. laughing or crying, or heightened irritability or temper). There is evidence that the  
116. risk of psychiatric adverse events is increased in children with a personal history  
117. of mood disorders, or who have a family history of mood disorders.

118. - problems with your heart (including heart defects) or an increased heartbeat.  
119. ATOXTRIN can increase your heart rate (pulse). Sudden death has been  
120. reported in patients with heart defects.

121. - high blood pressure. ATOXTRIN can increase blood pressure.

122. - low blood pressure. ATOXTRIN can cause dizziness or fainting in people with  
123. low blood pressure.

124. - problems with sudden changes in your blood pressure or your heart rate.

125. - Raynaud's phenomenon (a problem that causes decreased blood flow to the  
126. fingers).

127. - cardiovascular disease or past medical history of stroke.

128. - liver problems. You may need a lower dose.

129.

- 130. - psychotic symptoms including hallucinations (hearing voices or seeing things
- 131. which are not there), believing things that are not true or being suspicious.
- 132. - mania (feeling elated or over-excited, which causes unusual behaviour) and
- 133. agitation.
- 134. - aggressive feelings.
- 135. - unfriendly and angry (hostility) feelings.
- 136. - a history of epilepsy or have had seizures for any other reason. ATOXTRIN might
- 137. lead to an increase in seizure frequency.
- 138. - different moods than usual (mood swings) or feel very unhappy.
- 139. - hard-to-control, repeated twitching of any parts of the body or you repeat sounds
- 140. and words.
- 141. - difficulty emptying all the urine from your bladder.

142.

143. **Serotonin syndrome**

144. Serotonin syndrome is a potentially life-threatening condition which may occur when

145. taking [product name] in combination with some other medicines (see section 2

146. “Other medicines and ATOXTRIN”). Signs and symptoms of serotonin syndrome

147. may include a combination of the following: confusion, restlessness, incoordination

148. and rigidity, hallucinations, coma, fast heart beat, increased body temperature, fast

149. changes in blood pressure, sweating, flushing, tremor, overactive reflexes, nausea,

150. vomiting, and diarrhoea. Contact a doctor or go to your nearest emergency

151. department immediately if you think serotonin syndrome is happening to you.

152.

153. Treatment with ATOXTRIN may make you feel aggressive, hostile or violent; or

154. aggravate these symptoms if they were present before treatment. It may also cause

155. you to have unusual changes in behaviour or mood (including physical assault,

156. threatening behaviour and thoughts of harming others). If you or your family and/or  
157. friends notice any of these reactions, talk to your doctor or pharmacist right away.

158.

159. Tell your doctor or pharmacist if any of the above applies to you before starting  
160. treatment. This is because ATOXTRIN can make these problems worse. Your doctor  
161. will want to monitor how the medicine affects you.

162.

163. **Checks that your doctor will make before you start to take ATOXTRIN**

164. These checks are to decide if ATOXTRIN is the correct medicine for you. Your doctor  
165. will measure your:

166. - blood pressure and your heart rate (pulse) before and during the time you take  
167. ATOXTRIN.

168. - your height and weight if you are a child or teenager during the time you take  
169. ATOXTRIN.

170.

171. Your doctor will talk to you about:

172. - any other medicines you are taking.

173. - whether there is any family history of sudden unexplained death.

174. - any other medical problems (such as heart problems) you or your family may  
175. have.

176.

177. It is important that you provide as much information as you can. This will help your  
178. doctor decide if ATOXTRIN is the correct medicine for you. Your doctor may decide  
179. that other medical tests are needed before you start taking this medicine.

180.

181. **Important information about the content of the capsules**

182. Do not open ATOXTRIN capsules because the contents of the capsule can irritate  
183. the eye. If the contents of the capsules come into contact with the eye, the affected  
184. eye should be flushed immediately with water, and medical advice obtained. Hands  
185. and any other part of the body that may have come into contact with the capsule  
186. contents should also be washed as soon as possible.

187.

188. **Other medicines and ATOXTRIN**

189. Tell your doctor or pharmacist if you are taking, have recently taken or might take  
190. any other medicines. This includes non-prescription medicines. Your doctor will  
191. decide if you can take ATOXTRIN with your other medicines and in some cases your  
192. doctor may need to adjust your dose or increase your dose much more slowly.

193.

194. Do not take ATOXTRIN with medicines called MAOIs (monoamine oxidase inhibitors)  
195. used for depression. See section 2 “Do not take ATOXTRIN”.

196.

197. If you are taking other medicines, ATOXTRIN may affect how well they work or may  
198. cause side effects. If you are taking any of the following medicines, check with your  
199. doctor or pharmacist before taking ATOXTRIN:

- 200. - medicines that increase blood pressure or are used to control blood pressure.
- 201. - medicines such as antidepressants, for example imipramine, venlafaxine,  
202. mirtazapine, fluoxetine and paroxetine.
- 203. - some cough and cold remedies which contain medicines that can affect blood  
204. pressure. It is important to check with your pharmacist when you get any of these  
205. products.
- 206. - some medicines used to treat mental health conditions.

207.

208. - medicines that are known to increase the risk of seizures such as tricyclic  
209. antidepressants or SSRIs, neuroleptics, phenothiazines or butyrophenone,  
210. mefloquine, chloroquine, bupropion or tramadol.
211. - some medicines that cause ATOXTRIN to stay in the body for longer than normal  
212. (such as quinidine and terbinafine).
213. - salbutamol (a medicine to treat asthma) when taken by mouth or injected may  
214. make you feel as if your heart is racing, but this will not make your asthma worse.

215.

216. The medicines below may lead to an increased risk of an abnormal rhythm of the  
217. heart when taken with ATOXTRIN:

218. - medicines used to control the rhythm of the heart.
219. - medicines which change the concentration of salts in the blood.
220. - medicines for malaria prevention and treatment.
221. - some antibiotic medicines (such as erythromycin and moxifloxacin).

222.

223. ATOXTRIN may affect or be affected by other medicines. These include:

224. - Some anti-depressants, opioids as tramadol, and medicines used to treat migraine  
225. called triptans. These medicines may interact with [product name] and can lead to  
226. serotonin syndrome, a potentially life-threatening condition. (See section 2, Warnings  
227. and Precautions, Serotonin Syndrome).

228.

229. If you are not sure about whether any medicines you are taking are included in the  
230. list above, ask your doctor or pharmacist before taking ATOXTRIN.

231.

### 232. **Pregnancy and breastfeeding**

233. It is not known if this medicine can affect an unborn baby or pass into breast milk.

234. - This medicine should not be used during pregnancy unless your doctor has  
235. advised you to do so.

236. - You should either avoid taking this medicine if you are breastfeeding or  
237. discontinue breastfeeding.

238.

239. If you are pregnant or breastfeeding, think you may be pregnant, are planning to have  
240. a baby or planning to breastfeed your baby, ask your doctor or pharmacist for advice  
241. before taking this medicine.

242.

243. **Driving and using machines**

244. You may feel tired, sleepy or dizzy after taking ATOXTRIN. You should be careful if  
245. you are driving a car or operating machinery until you know how ATOXTRIN affects  
246. you. If you feel tired, sleepy or dizzy you should not drive or operate machinery.

247. It is not always possible to predict to what extent ATOXTRIN may interfere with the  
248. daily activities of a patient. Patients should ensure that they do not engage in the  
249. above activities until they are aware of the measure to which ATOXTRIN affects  
250. them.

251.

252. **3. How to take ATOXTRIN**

253. - Always take this medicine exactly as your doctor or pharmacist has told you.  
254. Check with your doctor or pharmacist if you are not sure. This is usually one or  
255. two times a day (morning and late afternoon or early evening).

256. - Children should not take this medicine without the help from an adult.

257. - If you are taking ATOXTRIN once a day and experience sleepiness or feel sick,  
258. your doctor may change your treatment schedule to twice a day.

259. - Oral use.

- 260.       -   The capsules should be swallowed whole, either with or without food.
- 261.       -   The capsules should not be opened and the contents inside the capsules should
- 262.           not be removed and taken in any other way.
- 263.       -   Taking the medicine at the same time each day may help you remember to take
- 264.           it.
- 265.       -   Treatment must be initiated by or under the supervision of a medical practitioner
- 266.           with appropriate knowledge and experience of childhood and/or adolescent
- 267.           behavioural disorders (for example, paediatrician or child/adolescent
- 268.           psychiatrist).
- 269.       -   The efficacy of ATOXTRIN beyond 18 months of treatment and safety of
- 270.           ATOXTRIN beyond 2 years of treatment has not been systematically evaluated.
- 271.       -   The safety and efficacy of ATOXTRIN in elderly patients have not been
- 272.           established.

273.

274.       **How much to take**

275.       **If you are a child or adolescent (6 years or older):**

276.       Your doctor will tell you how much ATOXTRIN you should take and will calculate this

277.       according to your weight. Your doctor will normally start you on a lower dose before

278.       increasing the amount of ATOXTRIN you need to take according to your body weight.

- 279.       -   Body weight up to 70 kg:
- 280.           a starting total daily dose of 0,5 mg per kg of body weight for a minimum of 7
- 281.           days. Your doctor may then decide to increase this to the usual maintenance
- 282.           dose of about 1,2 mg per kg of body weight daily.

- 283.       -   Body weight over 70 kg:

284.

285.

286. a starting total daily dose of 40 mg for a minimum of 7 days. Your doctor may  
287. then decide to increase this to the usual maintenance dose of 80 mg daily. The  
288. maximum recommended total daily dose is 80 mg.

289.

290. **Adults**

291. - ATOXTRIN should be started at a total daily dose of 40 mg for a minimum of 7  
292. days. Your doctor may then decide to increase this to the usual maintenance  
293. dose of 80 mg daily. The maximum recommended total daily dose is 80 mg.

294.

295. If you have problems with your liver your doctor may prescribe a lower dose.

296.

297. **Things your doctor will do when you are on treatment**

298. Your doctor will do some tests:

299. - before you start - to make sure that ATOXTRIN is safe and will be of benefit.  
300. - after you start - they will be done at least every 6 months, but possibly more often.

301.

302. They will also be done when the dose is changed. These tests will include:

303. - measuring height and weight in children and adolescents.  
304. - measuring blood pressure and heart rate.  
305. - checking whether you have any problems or if side effects have got worse while  
306. taking ATOXTRIN.

307.

308. Ongoing monitoring:

309. - Your heart health status will be regularly monitored with blood pressure and pulse  
310. recorded after each adjustment of dose and then at least every 6 months. For  
311. paediatric patients the use of a centile chart will be used by your doctor.

312.

313.

314.      **Withdrawal of Treatment:**

315.      -    in cases of significant adverse effects, ATOXTRIN may be stopped abruptly.

316.      -    ATOXTRIN may be discontinued without tapering the dose.

317.

318.      **Long-term treatment**

319.      ATOXTRIN does not need to be taken forever. If you take ATOXTRIN for more than  
320.      a year, your doctor will review your treatment, to see if the medicine is still needed.

321.

322.      **If you take more ATOXTRIN than you should**

323.      contact your doctor or the nearest hospital casualty department immediately and tell  
324.      them how many capsules you have taken. The most commonly reported symptoms  
325.      accompanying overdoses are gastrointestinal symptoms, sleepiness, dizziness,  
326.      tremor, and abnormal behaviour. Very rarely, serotonin syndrome has also been  
327.      reported, a potentially life-threatening condition. (See section 2, Warnings and  
328.      precautions, Serotonin Syndrome).

329.

330.      **If you forget to take ATOXTRIN**

331.      If you miss a dose, you should take it as soon as possible, but you should not take  
332.      more than your total daily dose in any 24-hour period. Do not take a double dose to  
333.      make up for a forgotten dose.

334.

335.      **If you stop taking ATOXTRIN**

336.      If you stop taking ATOXTRIN there are usually no side effects, but your ADHD  
337.      symptoms may return. You should talk to your doctor first before you stop treatment.

338.

339. If you have any further questions on the use of this medicine, ask your doctor or  
340. pharmacist.

341.

342. **4. Possible side effects**

343. Not all side effects reported for ATOXTRIN are included in this leaflet. Should your  
344. general health worsen or if you experience any untoward effects while taking  
345. ATOXTRIN, please consult your health care provider for advice. This medicine can  
346. cause side effects, although not everybody gets them. Your doctor will talk to you  
347. about these side effects.

348.

349. Some side effects could be serious. **If you have any of the side effects below, see**  
350. **a doctor straight away.**

351.

352. **Less Frequent**

- 353. - feeling or having a very fast heartbeat, abnormal rhythms of the heart
- 354. - thinking about or feeling like killing yourself
- 355. - feeling aggressive
- 356. - feeling unfriendly and angry (hostility)
- 357. - mood swings or mood changes
- 358. - serious allergic reaction with symptoms of
- 359. - swelling of the face and throat
- 360. - difficulty breathing
- 361. - hives (small raised, itchy patches of skin)
- 362. - seizures

363.

364. - psychotic symptoms including hallucinations (hearing voices or seeing things  
365. which are not there), believing things that are not true or being suspicious  
366.

367. **Children and adolescents aged under 18 have an increased risk of side effects**  
368. **such as:**

369. - thinking about or feeling like killing yourself  
370. - mood swings or mood changes  
371.

372. **Adults have a reduced risk of side effects such as:**

373. - seizures  
374. - psychotic symptoms including hallucinations (hearing voices or seeing things  
375. which are not there), believing things that are not true or being suspicious  
376.

377. **Less Frequent**

378. - liver injury  
379.

380. **You should stop taking ATOXTRIN and call your doctor immediately if you have**  
381. **any of the following:**

382. - dark urine  
383. - yellow skin or yellow eyes  
384. - tummy pain which is sore when you press it (tenderness) on the right side just  
385. below your ribs  
386. - a feeling of sickness (nausea) that is unexplained  
387. - tiredness  
388. - itching  
389. - feeling that you are coming down with flu

390.

391. **Other side effects reported include the following. If they get serious, tell your**  
 392. **doctor or pharmacist.**

393.

394.

395.

**Frequent side effects**

396.

**CHILDREN and****ADULTS**

397.

**ADOLESCENTS over 6 years**

398.

- headache

- feeling sick

399.

- pain in the stomach

- dry mouth

400.

- decreased appetite (not feeling

- headache

401.

hungry)

- decreased appetite (not feeling

402.

- feeling or being sick

hungry)

403.

- sleepiness

- problems getting to sleep, staying

404.

- increased blood pressure

asleep

405.

- increased heart rate (pulse)

- and waking early

406.

These effects may disappear after a while

- increased blood pressure

407.

in most patients.

- increased heart rate (pulse)

408.

- feeling or being sick (nausea)

409.

- being irritable or agitated

- feeling agitated

410.

- problems sleeping including waking

- decreased interest in sex

411.

early

- sleep disturbance

412.

- depression

- depression

413.

- feeling sad or hopeless

- feeling sad or hopeless

414.

- feeling anxious

- feeling anxious

415.

- tics

- dizziness

|      |                                        |                                      |
|------|----------------------------------------|--------------------------------------|
| 416. | - large pupils (the dark centre of the | - an abnormal taste or change in     |
| 417. | eye)                                   | taste that will not go away          |
| 418. | - dizziness                            | - tremor                             |
| 419. | - constipation                         | - tingling or numbness in the hands  |
| 420. | - loss of appetite                     | or feet                              |
| 421. | - upset stomach, indigestion           | - sleepiness, drowsy, feeling tired  |
| 422. | - swollen, reddened and itchy skin     | - constipation                       |
| 423. | - rash                                 | - stomach ache                       |
| 424. | - feeling lazy (lethargy)              | - indigestion                        |
| 425. | - chest pain                           | - wind (flatulence)                  |
| 426. | - tiredness                            | - being sick                         |
| 427. | - weight loss                          | - hot flush or flushing              |
| 428. |                                        | - feeling or having a very fast      |
| 429. |                                        | heartbeat                            |
| 430. |                                        | - swollen, reddened and itchy skin   |
| 431. |                                        | - increased sweating                 |
| 432. |                                        | - rash                               |
| 433. |                                        | - problems going to the toilet such  |
| 434. |                                        | as not be able to urinate, frequent  |
| 435. |                                        | or hesitant urinating, pain on       |
| 436. |                                        | urinating                            |
| 437. |                                        | - inflammation of the prostate gland |
| 438. |                                        | (prostatitis)                        |
| 439. |                                        | - groin pain in men                  |
| 440. |                                        | - failure to obtain an erection      |
| 441. |                                        | - retarded orgasm                    |

|      |  |                                      |
|------|--|--------------------------------------|
| 442. |  | - difficulty maintaining an erection |
| 443. |  | - menstrual cramps                   |
| 444. |  | - lack of strength or energy         |
| 445. |  | - tiredness                          |
| 446. |  | - feeling lazy (lethargy)            |
| 447. |  | - chills                             |
| 448. |  | - feeling, irritable, jittery        |
| 449. |  | - feeling thirsty                    |
| 450. |  | - weight loss                        |

451.

|      |                                           |                                     |
|------|-------------------------------------------|-------------------------------------|
| 452. | <b>Less frequent side effects</b>         |                                     |
| 453. | <b>CHILDREN and</b>                       | <b>ADULTS</b>                       |
| 454. | <b>ADOLESCENTS over 6 years</b>           |                                     |
| 455. | - fainting                                | - restlessness                      |
| 456. | - tremor                                  | - suicide-related events,           |
| 457. | - migraine                                | aggression, hostility and emotional |
| 458. | - blurred vision                          | lability                            |
| 459. | - eye infection (conjunctivitis)          | - tics                              |
| 460. | - abnormal skin sensation, such as        | - fainting                          |
| 461. | burning, prickling, itching, or tingling  | - migraine                          |
| 462. | - tingling or numbness in the hands or    | - blurred vision                    |
| 463. | feet                                      | - heart rhythm abnormal (QT         |
| 464. | - seizure (fits)                          | prolongation)                       |
| 465. | - feeling or having a very fast heartbeat | - feeling cold in fingers and toes  |
| 466. | (QT prolongation)                         | - chest pain                        |
| 467. | - shortness of breath                     | - shortness of breath               |

|      |                                            |                                      |
|------|--------------------------------------------|--------------------------------------|
| 468. | - increased sweating                       | - raised red itchy rashes (hives)    |
| 469. | - allergic reactions                       | - muscle spasms                      |
| 470. | - itchy skin                               | - an urge to urinate                 |
| 471. | - lack of strength or energy               | - abnormal or absence of orgasm      |
| 472. | - poor blood circulation which makes       | - irregular menstruation             |
| 473. | toes and fingers numb and pale             | - ejaculation failure                |
| 474. | (Raynaud's disease)                        | - poor blood circulation which makes |
| 475. | - problems going to the toilet such as     | toes and fingers numb and pale       |
| 476. | frequent or hesitant urinating, pain on    | (Raynaud's disease)                  |
| 477. | urinating                                  | - prolonged and painful erections    |
| 478. | - prolonged and painful erections          | - psychosis (including               |
| 479. | - groin pain in males                      | hallucinations)                      |
| 480. | - symptoms of liver disease / liver injury | - seizure                            |
| 481. |                                            | - symptoms of liver disease / liver  |
| 482. |                                            | injury                               |
| 483. |                                            |                                      |

484. **Frequency unknown side effects (Children):**

485. - Involuntary teeth grinding (bruxism)

486.

487. **Effects on growth**

488. Some children experience reduced growth (weight and height) when they start taking  
 489. ATOXTRIN. However, with long-term treatment, children recover to the weight and  
 490. height for their age range. Your doctor will watch your child's height and weight over  
 491. time. If your child is not growing or gaining weight as expected, your doctor may  
 492. change your child's dose or decide to stop ATOXTRIN temporarily.

493.

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

496.

497. **Reporting of side effects**

498. If you get side effects, talk to your doctor, pharmacist or nurse. You can also report  
499. side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found  
500. online under SAHPRA’s publications:  
501. <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can  
502. help provide more information on the safety of ATOXTRIN.

503.

504. **5. How to store ATOXTRIN**

505. • Store at or below 25 °C.
506. • Store all medicines out of reach of children.
507. • Do not store in a bathroom.
508. • Do not take after the expiry date stated on the label.
509. • Return all unused medicine to your pharmacist.
510. • Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

511.

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

513. **What ATOXTRIN contains**

514. - The active substance is Atomoxetine.

515. **ATOXTRIN 10 mg**

516. Each hard gelatine capsule contains 10 mg atomoxetine as 11,43 mg atomoxetine  
517. hydrochloride.

518. - The other ingredients are:

519.

520. Pregelatinized maize starch, colloidal anhydrous silica, dimeticone, gelatine,  
521. sodium lauryl sulfate (E487), titanium dioxide (E171), black imprinting ink.

522. **ATOXTRIN 18 mg**

523. Each hard gelatine capsule contains 18 mg atomoxetine as 20,57 mg atomoxetine  
524. hydrochloride.

525. - The other ingredients are:

526. Pregelatinized maize starch, colloidal anhydrous silica, dimeticone, gelatine,  
527. sodium lauryl sulfate (E487), titanium dioxide (E171), iron oxide yellow (E172),  
528. black imprinting ink.

529. **ATOXTRIN 25 mg**

530. Each hard gelatine capsule contains 25 mg atomoxetine as 28,57 mg atomoxetine  
531. hydrochloride.

532. - The other ingredients are:

533. Pregelatinized maize starch, colloidal anhydrous silica, dimeticone, gelatine,  
534. sodium lauryl sulfate (E487), titanium dioxide (E171), indigo carmine (E132),  
535. black imprinting ink.

536. **ATOXTRIN 40 mg**

537. Each hard gelatine capsule contains 40 mg atomoxetine as 45,71 mg atomoxetine  
538. hydrochloride.

539. - The other ingredients are:

540. Pregelatinized maize starch, colloidal anhydrous silica, dimeticone, gelatine,  
541. sodium lauryl sulfate (E487), titanium dioxide (E171), indigo carmine (E132),  
542. black imprinting ink.

543. **ATOXTRIN 60 mg**

544. Each hard gelatine capsule contains 60 mg atomoxetine as 68,57 mg atomoxetine  
545. hydrochloride.

546. - The other ingredients are:

547. Pregelatinized maize starch, colloidal anhydrous silica, dimeticone, gelatine,  
548. sodium lauryl sulfate (E487), titanium dioxide (E171), indigo carmine (E132), iron  
549. oxide yellow (E172), black imprinting ink.

550. **ATOXTRIN 80 mg**

551. Each hard gelatine capsule contains 80 mg atomoxetine as 91,42 mg atomoxetine  
552. hydrochloride.

553. - The other ingredients are:

554. Pregelatinized maize starch, colloidal anhydrous silica, dimeticone, gelatine,  
555. sodium lauryl sulfate (E487), titanium dioxide (E171), indigo carmine (E132), iron  
556. oxide yellow (E172), black imprinting ink.

557.

558. **What ATOXTRIN looks like and contents of the pack**

559. **ATOXTRIN 10 mg**

560. White powder in a hard gelatine capsule of size No 3, opaque white cap imprinted in  
561. black ink with '10' and opaque white body imprinted in black ink with 'mg'.

562. **ATOXTRIN 18 mg**

563. White powder in a hard gelatine capsule of size No 3, opaque rich yellow cap  
564. imprinted in black ink with '18' and opaque white body imprinted in black ink with  
565. 'mg'.

566. **ATOXTRIN 25 mg**

567. White powder in a hard gelatine capsule of size No 3, opaque blue cap imprinted in  
568. black ink with '25' and opaque white body imprinted in black ink with 'mg'

569. **ATOXTRIN 40 mg**

570. White powder in a hard gelatine capsule of size No 3, opaque blue cap imprinted in  
571. black ink with '40' and opaque blue body imprinted in black ink with 'mg.'

572.      **ATOXTRIN 60 mg**

573.      White powder in a hard gelatine capsule of size No 2, opaque blue cap imprinted in  
574.      black ink with '60' and opaque rich yellow body imprinted in black ink with 'mg'

575.      **ATOXTRIN 80 mg**

576.      White powder in a hard gelatine capsule of size No 2, opaque brown cap imprinted  
577.      in black ink with '80' and opaque white body imprinted in black ink with 'mg'.

578.

579.      ATOXTRIN is supplied in a cardboard box containing transparent PVC/PE/PCTFE-  
580.      Aluminium foil blisters or PA/AL/PVC- Aluminium foil blisters.

581.

582.      Pack sizes:

583.      7, 14, 28, 30 and 56 hard gelatine capsules.

584.      Not all packs and pack sizes may be marketed.

585.

586.      **Holder of Certificate of Registration**

587.      TRINITY PHARMA (PTY) LTD

588.      106, 16th Road,

589.      Midrand,

590.      1686,

591.      South Africa

592.

593.      **This leaflet was last revised in**

594.      19 August 2025

595.

**Registration Number(s)**

ATOXTRIN 10 mg:   55/1.2/0743

ATOXTRIN 18 mg: 55/1.2/0744

ATOXTRIN 25 mg: 55/1.2/0745

ATOXTRIN 40 mg: 55/1.2/0746

ATROXTRIN 60 mg: 55/1.2/0747

ATROXTRIN 80 mg: 55/1.2/0748

**Access to the corresponding Professional Information**

[www.trinitypharma.co.za](http://www.trinitypharma.co.za)