

1.	<u>APPROVED PATIENT INFORMATION LEAFLET</u>
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4.	SCHEDULING STATUS:
5.	S5
6.	
7.	
8.	ELAVEX 75 MG XR (Capsules)
9.	ELAVEX 150 MG XR (Capsules)
10.	
11.	Venlafaxine hydrochloride
12.	
13.	Read all of this leaflet carefully before you start taking ELAVEX XR
14.	<ul style="list-style-type: none"> • Keep this leaflet. You may need to read it again.
15.	<ul style="list-style-type: none"> • If you have further questions, please ask your doctor, or your pharmacist nurse or other health care provider.
16.	
17.	<ul style="list-style-type: none"> • ELAVEX XR 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.
18.	
19.	
20.	What is in this leaflet
21.	1. What ELAVEX XR is and what it is used for.
22.	2. What you need to know before you take ELAVEX XR .
23.	3. How to take ELAVEX XR .
24.	4. Possible side effects
25.	5. How to store ELAVEX XR .
26.	6. Contents of the pack and other information.
27.	
28.	1. WHAT ELAVEX XR IS AND WHAT IT IS USED FOR:

29.	
30.	ELAVEX XR contains the active ingredient venlafaxine. It belongs to a group of medicines called anti-
31.	depressants.
32.	ELAVEX XR is used to treat depression. It is also used to treat certain anxiety disorders or to relieve the
33.	symptoms of anxiety.
34.	
35.	2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ELAVEX XR:
36.	Do not take ELAVEX XR:
37.	<ul style="list-style-type: none">• If you are allergic to venlafaxine or any of the other ingredients of ELAVEX XR (see section 6).
38.	<ul style="list-style-type: none">• If you are also taking, or have taken within the last 14 days, any medicines known as irreversible
39.	monoamine oxidase inhibitors (MAOIs), used to treat depression or Parkinson's disease. Taking
40.	an irreversible MAOI together with ELAVEX XR , can cause serious or even life-threatening side
41.	effects. Also, you must wait at least 7 days after you stop taking ELAVEX XR before you take any
42.	MAOI.
43.	<ul style="list-style-type: none">• If you are a child under the age of 18 years.
44.	<ul style="list-style-type: none">• If you are pregnant or breastfeeding.
45.	
46.	
47.	<u>Warnings and precautions</u>
48.	Take special care with ELAVEX XR:
49.	<ul style="list-style-type: none">▪ If you use other medicines, such as triptans (used for migraine), or medicines used to treat
50.	depression called selective nor-adrenaline re-uptake inhibitors (SNRI's) or selective serotonin re-
51.	uptake inhibitors (SSRI's), tricyclics, or medicines containing lithium, which when taken together with
52.	ELAVEX XR could increase the risk of developing serotonin syndrome (see the section "Other
53.	medicines and ELAVEX XR).
54.	<ul style="list-style-type: none">• If you have eye problems, such as certain kinds of glaucoma (increased pressure in the eye).
55.	<ul style="list-style-type: none">• If you have a history of high blood pressure.
56.	<ul style="list-style-type: none">• If you have a history of heart problems.
57.	<ul style="list-style-type: none">• If you have a history of fits (seizures).

58.	<ul style="list-style-type: none">• If you have a history of low sodium levels in your blood (hyponatraemia).
59.	<ul style="list-style-type: none">• If you have a tendency to develop bruises or a tendency to bleed easily (history of bleeding disorders), or if you are taking other medicines that may increase the risk of bleeding e.g., warfarin (used to prevent blood clots).
60.	
61.	<ul style="list-style-type: none">• If you have a history of, or if someone in your family has had, mania or bipolar disorder (feeling over-excited or euphoric).
62.	
63.	<ul style="list-style-type: none">• If you have a history of aggressive behaviour.
64.	
65.	<ul style="list-style-type: none">• If you have been taking MAOI (monoamine oxidase inhibitors)
66.	
67.	<ul style="list-style-type: none">• Tell your doctor if you have high cholesterol levels.
68.	<ul style="list-style-type: none">• Tell your doctor if you experience problems with sexual response while taking ELAVEX XR.
69.	<ul style="list-style-type: none">• Tell your doctor if you notice you are unusually restless and have difficulty sitting or standing still.
70.	<ul style="list-style-type: none">• You may experience a dry mouth. Ensure that you maintain good oral hygiene while taking ELAVEX XR.
71.	
72.	<ul style="list-style-type: none">• Be aware that ELAVEX XR can have an effect on drug screening tests.
73.	
74.	
75.	Thoughts of suicide and worsening of your depression or anxiety disorder:
76.	If you are depressed and/or have anxiety disorders, you can sometimes have thoughts of harming or
77.	killing yourself. These may be increased when you first start taking ELAVEX XR .
78.	ELAVEX XR takes time to work, usually about two weeks, but sometimes longer.
79.	You may be more likely to have thoughts of:
80.	<ul style="list-style-type: none">• killing yourself or harming yourself.
81.	<ul style="list-style-type: none">• If you are a young adult less than 25 years old, with psychiatric conditions who were treated with
82.	an antidepressant.
83.	
84.	If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital
85.	straight away.
86.	

87.	You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety
88.	disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or
89.	anxiety is getting worse, or if they are worried about changes in your behaviour.
90.	
91.	Use in children and adolescents under 18 years of age
92.	ELAVEX XR should not be used for children and adolescents under 18 years.
93.	
94.	Other medicines and ELAVEX XR:
95.	Always tell your healthcare provider if you are taking any other medicine. (This includes all
96.	complementary or traditional medicines.)
97.	
98.	Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines,
99.	including medicines obtained without a prescription.
100.	Your doctor should decide whether you can take ELAVEX XR with other medicines. Do not start or stop
101.	taking any medicines, including those bought without a prescription, natural and herbal remedies, before
102.	checking with your doctor or pharmacist.
103.	
104.	Inform your doctor if you are taking any of the following medicines:
105.	<ul style="list-style-type: none">• Monoamine oxidase inhibitors, medicines used to treat depression or Parkinson's disease, must
106.	not be taken with ELAVEX XR . Tell your doctor if you have taken these medicines within the last
107.	14 days. (See the section "Before you take ELAVEX XR ").
108.	
109.	<ul style="list-style-type: none">• Serotonin syndrome:
110.	A potentially life-threatening condition known as serotonin syndrome, may occur with ELAVEX
111.	XR treatment, particularly when taken with other medicines, that work on your brain such as:
112.	<ul style="list-style-type: none">○ Triptans (used for migraine)
113.	<ul style="list-style-type: none">○ Other medicines to treat depression, for instance serotonin-norepinephrine re-uptake
114.	inhibitors (SNRI's eg, duloxetine), selective serotonin re-uptake inhibitors (SSRI's eg,
115.	citalopram, fluoxetine), tricyclics (eg, amitriptyline), or medicines containing lithium.

116.

117.

The following medicines may also interact with **ELAVEX XR** and should be used with caution. It is especially important to mention to your doctor or pharmacist if you are taking medicines containing:

119.

- Haloperidol or risperidone (to treat psychiatric conditions)

120.

- Metoprolol (to treat high blood pressure and heart problems)

121.

- Indinavir (to treat HIV)

122.

- Warfarin (to prevent blood clotting)

123.

- Cimetidine (to treat stomach ulcers)

124.

- Imipramine (to treat depression)

125.

126.

- Diazepam (to treat anxiety)

127.

- Medicines highly bound to plasma proteins in your blood (eg, warfarin)

128.

- Medicines metabolized by cytochrome P450 isoenzymes in your liver (e.g fluoxetine)

129.

- Lithium (to treat manic stage of bipolar disorder)

130.

- Weight loss medicines

131.

- Diabetes medicines (your doctor might need to adjust your dosage)

132.

- Medicines that affect your heart rhythm such as certain antibiotics (e.g., erythromycin, moxifloxacin), antipsychotic medicines (e.g., thioridazine), antihistamines

133.

134.

- Ketoconazole (an antifungal medicine)

135.

136.

- Oral contraceptives

137.

138.

ELAVEX XR with food and drink and alcohol:

139.

Take **ELAVEX XR** with food. Each capsule should be swallowed whole with fluid. Do not divide, crush, chew or place capsule in water.

140.

141.

You should avoid alcohol consumption while taking **ELAVEX XR**.

142.

143.

Pregnancy and breastfeeding:

144.

You should not use **ELAVEX XR** if you are pregnant or breastfeeding.

145.	If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please
146.	consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.
147.	
148.	ELAVEX XR passes into breast milk. There is a risk of an effect on the baby. Therefore, if you are
149.	breastfeeding your baby you should discuss the matter with your doctor, and he/she will decide whether
150.	you should stop breastfeeding or stop the therapy with ELAVEX XR .
151.	
152.	Driving and using machines:
153.	ELAVEX XR may cause drowsiness or blurred vision.
154.	It is not always possible to predict to what extent ELAVEX XR may interfere with your daily activities. Do
155.	not drive or use any tools or machines until you know how ELAVEX XR affects you.
156.	
157.	3. HOW TO TAKE ELAVEX XR:
158.	Do not share medicines prescribed for you with any other person.
159.	Always take ELAVEX XR exactly as your doctor has told you. You should check with your doctor or
160.	pharmacist if you are not sure.
161.	The usual recommended starting dose is 75 mg per day.
162.	Your doctor may change your dose, depending on how you respond to the treatment.
163.	
164.	Take ELAVEX XR at approximately the same time each day, either in the morning or in the evening.
165.	Capsules must be swallowed whole with fluid and not opened, crushed, chewed or dissolved. Take
166.	ELAVEX XR with food.
167.	
168.	Liver/kidney problems:
169.	Your doctor will reduce your dose depending on the severity of your liver or kidney problem.
170.	
171.	Elderly:
172.	Your doctor will decide on your dose.
173.	

174.	Maintenance, continuation and extended treatment:
175.	The need for you to use ELAVEX XR as a long term therapy will be assessed by your doctor.
176.	Do not stop taking ELAVEX XR without talking to your doctor (see the section “If you stop taking
177.	ELAVEX XR ”).
178.	
179.	If you take more ELAVEX XR than you should:
180.	In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the
181.	nearest hospital or poison control center.
182.	The symptoms of a possible overdose may include a rapid heartbeat, low blood pressure, low blood
183.	sugar, dizziness, seizures or fits, extreme tiredness or weakness, tingling, burning or prickling
184.	sensations, trembling or shaking and death.
185.	
186.	If you forget to take ELAVEX XR:
187.	If you miss a dose, take it as soon as you remember. However, if it is time for your next dose, skip the
188.	missed dose and take only a single dose as usual. Do not take more than the daily amount of ELAVEX
189.	XR that has been prescribed for you in one day.
190.	
191.	If you stop taking ELAVEX XR:
192.	Do not stop taking your treatment or reduce the dose without the advice of your doctor even if you feel
193.	better. If your doctor thinks that you no longer need ELAVEX XR , he/she may reduce your dose slowly
194.	before stopping treatment altogether. Side effects are known to occur when people stop using ELAVEX
195.	XR , especially when it is stopped suddenly or the dose is reduced too quickly.
196.	Your doctor will advise you on how you should gradually discontinue ELAVEX XR treatment. If you
197.	experience any symptoms that are troublesome, ask your doctor for further advice.
198.	
199.	4. POSSIBLE SIDE EFFECTS:
200.	ELAVEX XR can have side effects.
201.	
202.	

203.	Not all side effects reported for ELAVEX XR are included in this leaflet. Should your general health
204.	worsen while taking ELAVEX XR , please consult your doctor, pharmacist or other health care
205.	professional for advice.
206.	
207.	If any of the following happens, stop taking ELAVEX XR and tell your doctor immediately or go to the
208.	casualty department at your nearest hospital:
209.	<ul style="list-style-type: none">• Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty
210.	swallowing or breathing;
211.	<ul style="list-style-type: none">• itchy, lumpy rash (hives) or nettle rash (urticaria)
212.	These are all very serious side effects. If you have them, you may have had a serious reaction to
213.	ELAVEX XR . You may need urgent medical attention or hospitalisation.
214.	
215.	Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any
216.	of the following:
217.	<ul style="list-style-type: none">• Signs and symptoms of serotonin syndrome may include a combination of the following:
218.	<ul style="list-style-type: none"><ul style="list-style-type: none">○ restlessness, hallucinations, poor coordination, fast heartbeat, increased body temperature
219.	(fever), fast changes in blood pressure, overactive reflexes, diarrhoea, coma, nausea,
220.	vomiting, confusion, shivering, sweating, talking or acting with excitement you cannot
221.	control, trembling or shaking or twitching.
222.	<ul style="list-style-type: none">• You have muscle weakness, tenderness or pain, feel unwell or have a high temperature. You may
223.	have a condition called "rhabdomyolysis" which is a breakdown of muscle tissue.
224.	<ul style="list-style-type: none">• You get blistering or peeling of the skin around your lips, eyes, mouth, nose and genitals, with flu-like
225.	symptoms and fever. These could be signs an illness called "Stevens-Johnson syndrome"
226.	<ul style="list-style-type: none">• You have a very high temperature, sweating, stiff muscles, fast heart rate, fast breathing and
227.	drowsiness or confusion. You may also have difficulty walking, have twitching or jerking movements
228.	you cannot control. These could be signs of a condition called Neuroleptic Malignant Syndrome.
229.	
230.	Tell your doctor as soon as possible if:
231.	

232. • You notice yellowing of your skin or eyes and your urine becomes darker in colour. You may also
233. have a high temperature, feel tired, lose your appetite, have stomach pain or feel sick. These could
234. be signs of a liver problem, such as jaundice or hepatitis
235. • You get severe stomach pain which may reach through to your back. This could be a sign of
236. pancreatitis
237. • You feel unwell, lose your appetite, have a fever lasting 2 to 3 days, have difficulty breathing,
238. shortness of breath and a cough. This could be due to a lung problem (pulmonary eosinophilia)
239. • You have fits (seizures) or, in patients with epilepsy, you notice an increase in the number of
240. seizures
241. • You feel 'high' or over-excited, see or hear things which are not there (hallucinations) and have
242. difficulty concentrating or staying still (mania, hypomania or delirium)
243. • You feel unwell, confused, irritable or weak. You may also lose your appetite. This could be a
244. condition called Syndrome of Inappropriate Anti-Diuretic Hormone Secretion (SIADH)
245. • You have painful eyes with blurred vision. These could be signs of glaucoma (increased pressure in
246. the eye)
- 247.
248. **Tell your doctor if any of the following:**
249. Frequent side effects:
250. • Feeling sick (nausea)
251. • Dry mouth, headache
252. • Sweating more than usual
253. • Heart problems including high blood pressure (hypertension), palpitations, hot flushes
254. • Weight loss
255. • Changes in your sense of taste
256. • Loss of appetite (anorexia), being sick (vomiting), constipation
257. • Stomach pains, shivering, fever
258. • Sore joints or muscles, stiff or tense muscles
259. • Feeling restless, nervous, shaking, anxious or confused
260. • Numbness, tingling, pricking, burning, or a creeping feeling on the skin (paraesthesia)

261.	<ul style="list-style-type: none">• Passing urine more or less often than usual
262.	<ul style="list-style-type: none">• Reduced sex drive
263.	<ul style="list-style-type: none">• Menstrual cycle changes in women such as increased bleeding or irregular bleeding
264.	<ul style="list-style-type: none">• Difficulty breathing or shortness of breath, yawning
265.	<ul style="list-style-type: none">• Problems with your eyesight
266.	<ul style="list-style-type: none">• Feeling dizzy or weak
267.	<ul style="list-style-type: none">• Being drowsy, finding it difficult to sleep or having strange dreams
268.	<ul style="list-style-type: none">• Difficulty having an orgasm (in both men and women), problems with getting or keeping an erection
269.	<ul style="list-style-type: none">• (impotence)
270.	<ul style="list-style-type: none">• Feeling separated or detached from reality
271.	
272.	<u>Less frequent side effects:</u>
273.	<ul style="list-style-type: none">• Feeling faint or light-headed especially when standing up quickly. These could be signs of low blood
274.	<ul style="list-style-type: none">• pressure
275.	<ul style="list-style-type: none">• Fainting
276.	<ul style="list-style-type: none">• Heart problems including an abnormal heartbeat, a faster or slower than usual heart rate
277.	<ul style="list-style-type: none">• Grinding and clenching of teeth whilst sleeping
278.	<ul style="list-style-type: none">• Muscle cramp (spasm), including twitching muscles
279.	<ul style="list-style-type: none">• Lack of emotion or interest in things (apathy), seeing or hearing things which are not there
280.	<ul style="list-style-type: none">• (hallucinations)
281.	<ul style="list-style-type: none">• Feeling anxious, depressed, changes in mood, sleepiness
282.	<ul style="list-style-type: none">• Difficulty balancing or coordinating movement
283.	<ul style="list-style-type: none">• Difficulty passing urine
284.	<ul style="list-style-type: none">• Being more sensitive to sunlight (or artificial UV light) than usual (photosensitivity)
285.	<ul style="list-style-type: none">• Hair loss
286.	<ul style="list-style-type: none">• Changes in the way things taste
287.	<ul style="list-style-type: none">• Diarrhoea
288.	<ul style="list-style-type: none">• Skin rash
289.	

290.	<ul style="list-style-type: none"> • Ringing in your ears (tinnitus)
291.	<ul style="list-style-type: none"> • A feeling of spinning (vertigo)
292.	<ul style="list-style-type: none"> • Widespread bruising
293.	<ul style="list-style-type: none"> • Feeling aggressive or having aggressive thoughts – this is more likely at the start of, and after
294.	stopping, treatment
295.	<ul style="list-style-type: none"> • Chest pain
296.	<ul style="list-style-type: none"> • Feeling very confused, unsettled and unable to think clearly
297.	<ul style="list-style-type: none"> • Bruising more easily than usual, bleeding more or for longer than usual after an injury, unusual
298.	bleeding from the gums or elsewhere, a rash of purple dark red spots under the skin, getting
299.	infections more easily than usual. These could be signs of a blood problem.
300.	<ul style="list-style-type: none"> • Thoughts of harming or killing yourself.
301.	
302.	If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.
303.	
304.	Reporting of side effects
305.	If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to
306.	SAHPRA via the “ 6.04 Adverse Drug Reaction Reporting Form ”, found online under SAHPRA’s
307.	publications: https://www.sahpra.org.za/Publications/Index/8 . By reporting side effects, you can help
308.	provide more information on the safety of ELAVEX XR .
309.	
310.	5. HOW TO STORE ELAVEX XR
311.	Store in a cool, dry place at or below 25 °C.
312.	Keep the blister strips in the outer carton until required for use.
313.	Store in unit carton until before use.
314.	KEEP OUT OF REACH OF CHILDREN
315.	Do not use after the expiry date stated on the carton. Return all unused medicine to your pharmacist.
316.	Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
317.	
318.	6. CONTENTS OF THE PACK AND OTHER INFORMATION

319.	What ELAVEX XR contains:
320.	ELAVEX 75 mg XR: Each extended release capsule contains venlafaxine hydrochloride equivalent to
321.	75 mg venlafaxine.
322.	ELAVEX 150 mg XR: Each extended release capsule contains venlafaxine hydrochloride equivalent to
323.	150 mg venlafaxine.
324.	
325.	The inactive ingredients are:
326.	<ul style="list-style-type: none">• ELAVEX 75 mg XR capsules contain: Eudragit RS 100, Eudragit E 12,5, hypromellose, sodium
327.	lauryl sulphate, magnesium stearate, titanium dioxide (E171), red iron oxide (E172), gelatin.
328.	<ul style="list-style-type: none">• ELAVEX 150 mg XR capsules contain: Eudragit RS 100, Eudragit E 12,5, hypromellose,
329.	sodium lauryl sulphate, magnesium stearate, titanium dioxide (E171), erythrosine (E127), indigo
330.	carmin (E132), gelatin.
331.	
332.	What ELAVEX XR looks like and contents of the pack
333.	ELAVEX 75 mg XR: Flesh opaque-flesh opaque No. 0, hard gelatin capsules, containing two 37,5 mg
334.	tablets.
335.	ELAVEX 150 mg XR: Scarlet opaque-scarlet opaque No. 00, hard gelatin capsules, containing three 50
336.	mg tablets.
337.	
338.	ELAVEX XR capsules are packed as follows:
339.	ELAVEX 75 mg XR: is packaged in an opaque white PVC/PE/PVDC/ Aluminium blister foil. There are 3
340.	blister strips of 10 capsules each, packed in an outer cardboard box as a pack size of 30 capsules.
341.	ELAVEX 150 mg XR: is packaged in an opaque white PVC/PE/PVDC/ Aluminium blister foil. There are
342.	3 blister strips of 10 capsules each, packed in an outer cardboard box as a pack size of 30 capsules.
343.	
344.	HOLDER OF THE CERTIFICATE OF
345.	REGISTRATION:
346.	Accord Healthcare (Pty) Ltd
347.	Building 31, Ground Floor,

Applicant/HCR: Accord Healthcare (Pty) Ltd
Product Name: Elavex 75 mg XR and Elavex 150 mg XR
Strength: 75 mg/150 mg venlafaxine hydrochloride per extended release capsule

348.	Woodlands Office Park,
349.	20 Woodlands Drive, Woodmead,
350.	Johannesburg, 2191
351.	Tel: +27 11 234 5701/2
352.	Email: medinfo@accordhealth.co.za
353.	
354.	This leaflet was last revised in
355.	30 September 2024
356.	
357.	REGISTRATION NUMBER:
358.	ELAVEX 75 mg XR: 43/1.2/0138
359.	ELAVEX 150 mg XR: 43/1.2/0139
360.	