

1.	ANNOTATED AMENDED PROPOSED PATIENT INFORMATION	
2.	LEAFLET	
3.		
4.	SCHEDULING STATUS: S5	
5.		
6.	XANOR® 0,25 mg tablets	
7.	XANOR® 0,5 mg tablets	
8.	XANOR® 1,0 mg tablets	
9.	XANOR® 2,0 mg tablets	
10.	XANOR® SR 0,5 mg tablets	
11.	XANOR® SR 1,0 mg tablets	
12.	XANOR® SR 2,0 mg tablets	
13.	Alprazolam	
14.		
15.	Read all of this leaflet carefully before you start taking XANOR	
16.	<ul style="list-style-type: none"> • Keep this leaflet. You may need to read it again. 	
17.	<ul style="list-style-type: none"> • If you have further questions, please ask your doctor, pharmacist, 	
18.	nurse or other health care provider.	
19.	<ul style="list-style-type: none"> • XANOR has been prescribed for you personally and you should not 	
20.	share your medicine with other people. It may harm them, even if	
21.	their symptoms are the same as yours.	
22.		
23.	What is in this leaflet	
24.	1. What XANOR is and what it is used for	
25.	2. What you need to know before you take XANOR	
26.	3. How to take XANOR	
27.	4. Possible side effects	
28.	5. How to store XANOR	

29.	6. Contents of the pack and other information	
30.		
31.	1. What XANOR is and what it is used for	
32.	XANOR belongs to a group of medicines known as benzodiazepines.	
33.	It is used in the treatment of anxiety, certain types of depression and	
34.	panic disorders.	
35.		
36.	2. What you need to know before you take XANOR	
37.	Do not take XANOR:	
38.	<ul style="list-style-type: none"> • if you have ever had any unusual or allergic reaction to alprazolam 	Amended as per recommendation
39.	or to any of the ingredients of XANOR or other similar medications.	
40.	Also tell your doctor if you are allergic to any other substances such	
41.	as foods, preservatives or dyes.	
42.	<ul style="list-style-type: none"> • if you are pregnant, trying to become pregnant or breastfeeding. 	Amended as per recommendation
43.	Your baby may become dependent on this medicine XANOR or	
44.	experience breathing problems, difficulty in feeding, body	
45.	temperature problems or muscle weakness. Breastfed babies may	
46.	become drowsy as XANOR may pass into the breast milk.	
47.	<ul style="list-style-type: none"> • if you suffer from schizophrenia. 	
48.	<ul style="list-style-type: none"> • if you are using ketoconazole <u>and itraconazole.</u> 	Added in alignment to PI
49.	<ul style="list-style-type: none"> • <u>when used in children underbelow 18 years of age, as these</u> 	Moved from Warnings and precautions below in alignment to PI, and amended as per recommendation
50.	<u>patients are more sensitive than adults to the effects of XANOR.</u>	
51.	<ul style="list-style-type: none"> • <u>if you suffer from a disease called 'myasthenia gravis' where you</u> 	Added in alignment to PI and as per recommendation; UK PIL pg 1, para 7, pg 2, para 1
52.	<u>suffer from very weak and tired muscles.</u>	
53.	<ul style="list-style-type: none"> • <u>if you have severe chest problems or breathing difficulties (e.g.</u> 	
54.	<u>chronic bronchitis or emphysema).</u>	
55.	<ul style="list-style-type: none"> • <u>if you have 'sleep apnoea' – this is a condition where your breathing</u> 	

56.	<u>becomes irregular, even stopping for short periods, while you are</u>	
57.	<u>asleep.</u>	
58.	• <u>if you have severe liver problems.</u>	
59.	Warnings and precautions	
60.	Take special care with XANOR:	
61.	• <u>benzodiazepines and related products should be used with caution</u>	Added in alignment to PI; UK PIL pg 2, para 3
62.	<u>in elderly, due to the risk of sedation and/or musculoskeletal</u>	
63.	<u>weakness that can promote falls, often with serious consequences</u>	
64.	<u>in this population.</u>	
65.	• if you suffer from kidney or liver disease – this may increase the	Amended as per recommendation
66.	chances of experiencing side effects with XANOR.	
67.	• if you have a serious condition affecting your breathing.	
68.	• <u>if you suffer from anxiety together with underlying depression</u>	Added in alignment to PI
69.	• <u>if you are taking sedatives (barbiturates).</u>	
70.	• if you have a history of <u>using too much alcohol regularly, or</u> alcohol	Amended as per recommendation
71.	abuse.	
72.	• When used in children under 18 years as these patients are more	Moved above to Do not take XANOR, in alignment to PI
73.	sensitive than adults to the effects of XANOR.	
74.	• if you have a history of drug abuse or dependence – <u>as</u>	Amended as per recommendation
75.	dependence on XANOR may occur <u>more easily.</u>	
76.	• if you have epilepsy or a history of seizures – the risk of seizures	
77.	may be increased when starting or suddenly stopping XANOR	
78.	treatment.	
79.	• W <u>h</u> en stopping your XANOR medication too quickly or abruptly –	
80.	you may experience withdrawal symptoms like inability to sleep,	
81.	stomach or muscle cramps, vomiting, sweating,	
82.	convulsions/seizures.	
83.	• if you have severe mental illness.	Amended as per recommendation

84.	<ul style="list-style-type: none"> • if you suffer from depression, unless there is some anxiety 	
85.	<ul style="list-style-type: none"> • <u>with forms part of</u> the depression. 	
86.	<ul style="list-style-type: none"> • <u>if you have ever felt so depressed that you have thoughts about</u> 	Added in alignment to PI; UK PIL pg 2, para 2
87.	<ul style="list-style-type: none"> • <u>taking your own life.</u> 	
88.	<ul style="list-style-type: none"> • <u>concomitant use of XANOR and opioids (strong pain killers,</u> 	Added in alignment to PI; UK PIL pg 2, para 7, pg 3, para 1
89.	<ul style="list-style-type: none"> • <u>medicines for substitution therapy and some cough medicines)</u> 	
90.	<ul style="list-style-type: none"> • <u>increases the risk of drowsiness, difficulties in breathing</u> 	
91.	<ul style="list-style-type: none"> • <u>(respiratory depression), coma and may be life-threatening.</u> 	
92.	<ul style="list-style-type: none"> • <u>Because of this, concomitant use should only be considered when</u> 	
93.	<ul style="list-style-type: none"> • <u>other treatment options are not possible. However, if your doctor</u> 	
94.	<ul style="list-style-type: none"> • <u>does prescribe XANOR together with opioids, the dosage and</u> 	
95.	<ul style="list-style-type: none"> • <u>duration of concomitant treatment should be limited by your</u> 	
96.	<ul style="list-style-type: none"> • <u>doctor. Please tell your doctor about all opioid medicines you are</u> 	
97.	<ul style="list-style-type: none"> • <u>taking and follow your doctor's dosage recommendation closely.</u> 	
98.	<ul style="list-style-type: none"> • <u>It could be helpful to inform friends or relatives to be aware of sign</u> 	
99.	<ul style="list-style-type: none"> • <u>and symptoms stated above. Contact your doctor when</u> 	
100.	<ul style="list-style-type: none"> • <u>experiencing such symptoms.</u> 	
101.	<ul style="list-style-type: none"> • <u>if you experience memory loss (amnesia). Tell your doctor straight</u> 	Added in alignment to PI; UK PIL pg 5, para 2
102.	<ul style="list-style-type: none"> • <u>away.</u> 	
103.	<ul style="list-style-type: none"> • <u>if you feel that XANOR is not working anymore. Some loss of</u> 	Added in alignment to PI
104.	<ul style="list-style-type: none"> • <u>effectiveness of XANOR may occur after repeated use for a few</u> 	
105.	<ul style="list-style-type: none"> • <u>weeks.</u> 	
106.	<p>Other medicines and XANOR</p>	
107.	Always tell your health care provider if you are taking any other	
108.	medicine. (This includes complementary or traditional medicines). The	
109.	use of XANOR with these medicines may cause undesirable	
110.	interactions.	
111.	<ul style="list-style-type: none"> • Imipramine and desipramine: XANOR may increase the levels of 	

112.	these medicines in the body if taken together.	
113.	<ul style="list-style-type: none"> <u>Some strong pain killers (e.g. opioids such as morphine, codeine or propoxyphene): using these medicines together with XANOR increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening.</u> 	Added in alignment to PI; UK PIL pg 2, para 5, 7
114.		
115.		
116.		
117.	<ul style="list-style-type: none"> <u>Antipsychotic medicines used to treat mental illnesses like schizophrenia.</u> 	Added in alignment to PI; UK PIL pg 2, para 5
118.		
119.	<ul style="list-style-type: none"> Do not take XANOR with ketoconazole, itraconazole or other azole antifungal medicines (used to treat fungal infections). 	
120.		
121.	<ul style="list-style-type: none"> It is recommended that theYour dose of XANOR <u>should</u> be decreased if/when you are given with nefazodone, fluvoxamine or cimetidine – higher blood levels of XANOR may occur and this can lead to more side effects. Your doctor may want to change the dose of XANOR or give you a different medicine. 	Amended as per recommendation
122.		
123.		
124.		
125.		
126.	<ul style="list-style-type: none"> Caution is recommendedTake special care if/-when you are given XANOR is given with any of the following medicines: fluoxetine, oral contraceptives (birth control pill), sertraline, diltiazem or macrolide antibiotics (e.g. erythromycin <u>and troleandomycin</u>). 	Amended as per recommendation Added in alignment to PI
127.		
128.		
129.		
130.	<ul style="list-style-type: none"> <u>Ritonavir or other similar medicines used for treating HIV.</u> 	Added in alignment to PI; UK PIL pg 2, para 5
131.	<ul style="list-style-type: none"> <u>Digoxin (used to treat various heart conditions).</u> 	
132.	<u>XANOR with alcohol</u>	Added in alignment to PI; UK PIL pg 3, para 2
133.	<u>It is important not to drink any alcohol while you are taking XANOR, as</u>	
134.	<u>alcohol increases the effects of the medicine.</u>	
135.	Pregnancy and breastfeeding	
136.	Your doctor will decide if XANOR is appropriate for you.	
137.	If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking XANOR.	
138.		
139.		

140.	Driving and using machines	
141.	XANOR may cause drowsiness or dizziness. If you feel drowsy, do not	
142.	drive or do anything that requires you to be alert.	
143.	It is not always possible to predict to what extent XANOR may interfere	Amended as per recommendation
144.	with theyour daily activities of a patient . Patients <u>You</u> should ensure	
145.	that theyyou do not engage in the above activities <u>that require you to</u>	
146.	<u>be alert</u> until theyyou are aware of the measure to which XANOR	
147.	affects them.	
148.	XANOR contains lactose	
149.	Patients with rare hereditary problems of galactose intolerance,	Amended to comply with Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use' (SANTE-2017-11668) EMA/CHMP/302620/2017/EN corr. 1, as per latest PI guideline
150.	the Lapp lactase deficiency or glucose-galactose malabsorption	
151.	should not take this medicine. <u>If you have been told by your doctor</u>	
152.	<u>that you have an intolerance to some sugars, contact your doctor</u>	
153.	<u>before taking this medicinal product.</u>	
154.		
155.	3. How to take XANOR	
156.	Do not share medicines prescribed for you with any other person.	
157.	Always take XANOR exactly as your doctor has told you. Your doctor	
158.	will decide what dose is right for you. Check with your doctor or	
159.	pharmacist if you are not sure.	
160.	The usual dose of XANOR varies from one person to another. In	
161.	patients who require higher doses, your doctor will choose the right	
162.	dose for you.	
163.	XANOR tablets	
164.	<u>Your doctor will decide what is the usual or appropriate dose for your</u>	Added as per recommendation
165.	<u>condition.</u>	
166.	<i>A. For anxiety</i>	
167.	The usual starting dose is 0,25 mg to 0,5 mg taken three times a day.	

168.	Your doctor may increase your dose if needed. However, the <u>usual</u>	Amended as per recommendation
169.	dose usually <u>for this</u> is not more than 4 mg a day.	
170.	<i>B. For mixed anxiety/depression</i>	
171.	The usual starting dose is 0,5 mg taken three times a day. Your doctor	Amended as per recommendation
172.	may increase your dose if needed. However, the dose <u>is</u> usually is-not	
173.	more than 4,5 mg a day.	
174.	<i>C. For panic disorders</i>	
175.	The usual starting dose is 0,5 mg to 1,0 mg given at bedtime or 0,5	Amended as per recommendation
176.	mg taken three times a day. Your doctor may increase your dose if	
177.	needed. However, the <u>usual</u> dose usually is not more than 10 mg a	
178.	day.	
179.	<i>D. For elderly patients</i>	
180.	The usual starting dose is 0,25 mg taken two or three times a day.	Amended as per recommendation
181.	Your doctor may increase your dose if needed. However, the dose <u>is</u>	
182.	usually is-not more than 0,75 mg a day.	
183.	XANOR SR tablets	
184.	<u>These</u> tablets should be taken intact; they should not be chewed,	Amended as per recommendation
185.	crushed or broken. <u>They should be swallowed whole.</u>	
186.	<i>A. For anxiety or mixed anxiety/depression</i>	
187.	The usual starting dose is 1 mg daily, <u>taken</u> in one or two doses. Your	Amended as per recommendation
188.	doctor may increase your dose if needed. However, the dose <u>is</u> usually	
189.	is-not more than 4 mg a day.	
190.	<i>B. For panic disorders</i>	
191.	The usual starting dose is 0,5 mg to 1,0 mg given at bedtime or 0,5	
192.	mg taken two times a day. Your doctor may increase your dose if	
193.	needed. However, the dose usually is not more than 10 mg a day.	
194.	<i>C. For elderly patients</i>	
195.	The usual starting dose is 0,5 mg to 1,0 mg taken one or two times a	

196.	day. Your doctor may increase your dose if needed. However, the	
197.	dose usually is not more than 1 mg a day.	
198.	Your doctor will tell you how long your treatment with XANOR will last.	
199.	Do not alter the dose yourself without your doctor's advice. Do not	
200.	stop taking XANOR unless told to do so by your doctor. Should you	
201.	need to stop taking XANOR, your doctor will have decided the best	
202.	method for you.	
203.	If you have the impression that the effect of XANOR is too strong or	
204.	too weak <u>for you</u> , tell your doctor or pharmacist.	Amended as per recommendation
205.	If you take more XANOR than you should	
206.	If you take more XANOR than you should, it can become habit-forming	
207.	(causing mental or physical dependence). In the event of overdose,	
208.	consult your doctor or pharmacist. If neither is available, contact the	
209.	nearest hospital or poison centre. Always take the labelled medicine	
210.	package with you, whether there are any XANOR left or not.	
211.	These are the possible signs and symptoms of overdose: slurred	
212.	speech or confusion, severe drowsiness, staggering or walking	
213.	unsteadily, difficulty breathing or coma.	
214.	If you forget to take XANOR	
215.	If you forget to take <u>ayour dose of XANOR</u> , take it as soon as you	Amended as per recommendation
216.	remember. Then take any remaining doses for that day at regular	
217.	spaced intervals. Do not take two doses at the same time. If you	
218.	forget to take <u>your medicine XANOR</u> for more than one week, call your	
219.	doctor before taking any more medicine.	
220.		
221.	4. Possible side effects	
222.	XANOR can have side effects.	
223.	Some side effects of XANOR include the following, and should <u>also be</u>	Amended as per recommendation

224.	discussed with your doctor if they occur:	
225.	<i>Frequency unknown:</i>	
226.	Peripheral oedema (swelling of hands and feet due to the retained	
227.	fluids) and angioedema (swelling beneath the skin).	
228.	<i>Frequent:</i>	
229.	Anorexia (lack or loss of appetite for food), confusion (more common	
230.	in the elderly), depression, irritability, changes in sexual desire,	
231.	dizziness, headache, lack of memory, blurred vision (not seeing	
232.	clearly), constipation, nausea, feeling tired, dry mouth.	
233.	<i>Less frequent:</i>	
234.	Aggressive behaviour, insomnia (inability to sleep), mood changes,	
235.	nervousness, amnesia (lack loss of memory), tremor (trembling or	Amended as per recommendation
236.	shakiness), diarrhoea, vomiting, muscle twitching or weakness,	
237.	changes in menstrual period cycle, changes in weight, hallucinations	
238.	(seeing, hearing or feeling things that are not there), agitation, rage	
239.	(uncontrolled anger), slurred speech, itching.	
240.	Not all side effects reported for XANOR are included in this leaflet.	
241.	Should your general health worsen or if you experience any untoward	
242.	effects while taking XANOR, please consult your health care provider	
243.	for advice.	
244.	If you notice any side effects not mentioned in this leaflet, please	
245.	inform your doctor or pharmacist.	
246.	Reporting of side effects	
247.	If you get side effects, talk to your doctor or pharmacist. You can also	
248.	report side effects to SAHPRA via the “ 6.04 Adverse Drug Reaction	
249.	Reporting form ”, found online under SAHPRA’s publications:	
250.	https://www.sahpra.org.za/Publications/Index/8 . By reporting side	
251.	effects, you can help provide more information on the safety of	

252.	XANOR.	
253.		
254.	5. How to store XANOR	
255.	Store at or below 30 25 °C.	As per Type IA _{IN} overall variations dated 27 Sep 2019 (implemented 07 Oct 2019), the storage condition has been aligned to the outcome discussed in Module 3.2.P.8.1 Stability summary and conclusion
256.	Keep tablets packed in bottles tightly closed.	
257.	Store all medicines out of reach of children.	
258.	Do not use after the expiry date stated on the label.	
259.	Return all unused medicine to your pharmacist.	
260.	Do not dispose of unused medicine in drains or sewerage systems	
261.	(e.g. toilets).	
262.		
263.	6. Contents of the pack and other information	
264.	What XANOR contains	
265.	The active ingredient of XANOR is alprazolam.	
266.	XANOR contains the following inactive ingredients:	
267.	XANOR tablets: Colloidal silicon dioxide, docusate sodium with sodium	
268.	benzoate, lactose hydrous, magnesium stearate, microcrystalline	
269.	cellulose and starch with erythrosine sodium or FD & C blue as	
270.	colourants.	
271.	XANOR SR tablets: Cellulose methylhydroxypropyl, lactose anhydrous,	
272.	magnesium stearate, and silicon colloidal dioxide with FD & C blue as	
273.	colourant.	
274.	What XANOR looks like and contents of the pack	
275.	XANOR 0,25 mg tablets are white, ovoid shaped, embossed with	

276.	"Upjohn 29" on the one side and scored on the other side.	
277.	XANOR 0,5 mg tablets are pink, ovoid shaped, embossed with	
278.	"Upjohn 55" on the one side and scored on the other side.	
279.	XANOR 1,0 mg tablets are lavender, ovoid shaped, embossed with	
280.	"Upjohn 90" on the one side and scored on the other side.	
281.	XANOR 2,0 mg tablets are white capsule shaped, three scored tablets,	
282.	embossed with "U94".	
283.	XANOR SR 0,5 mg tablets are light round, blue, round deep oval	As per Type IA _{IN} overall variations dated 27 Sep 2019 (implemented 07 Oct 2019), the wording for Appearance of the SR tablet has been simplified for clarity in alignment to Module 3.2.P.5.1 Specifications.
284.	shape convex tablets, embossed with "P&U 57" on one side.	
285.	XANOR SR 1,0 mg tablets are white, round, white deep oval shape,	
286.	convex tablets embossed with "P&U 59" on one side.	
287.	XANOR SR 2,0 mg tablets are light blue, pentagonal deep oval shape,	
288.	blue tablets embossed with "P&U 66" on one side.	
289.	XANOR 0,25 mg and 1,0 mg are packed in blister packs of 30 and 100	
290.	tablets.	
291.	XANOR 0,5 mg is packed in blister packs of 30 and 100 tablets and in	
292.	bottles containing 500 tablets.	
293.	XANOR 2,0 mg is packed in bottles containing 30 and 100 tablets.	
294.	XANOR SR tablets are packed in foil blisters of 60 tablets.	
295.		
296.	Holder of Certificate of Registration	
297.	Pfizer Laboratories (Pty) Ltd	
298.	85 Bute Lane	
299.	Sandton	
300.	2196	
301.	South Africa	
302.	Tel.: +27(0)11 320 6000 / 0860 734 937 (Toll-free South Africa)	
303.		

304.	This leaflet was last revised in	
305.	07 March 2014	
306.		
307.	Registration numbers	
308.	XANOR 0,25 mg tablets: M/2.6/233	
309.	XANOR 0,5 mg tablets: M/2.6/234	
310.	XANOR 1,0 mg tablets: M/2.6/235	
311.	XANOR 2,0 mg tablets: 27/2.6/0096	
312.	XANOR SR 0,5 mg tablets: 29/2.6/0504	
313.	XANOR SR 1,0 mg tablets: 29/2.6/0505	
314.	XANOR SR 2,0 mg tablets: 29/2.6/0506	