

Applicant: Aurogen South Africa (Pty) Ltd
Product Name: ROLIXIRD 450 MG
Dosage form and strength: Tablet, Each film coated tablet contains 496.36 mg of Valganciclovir Hydrochloride equivalent to 450 mg of Valganciclovir.

MODULE 1
 1.3.2
Date: 2020.02.03
Submitted date: 2020.09.25

1.3.2 Patient Information Leaflet cleaned approved

LINE NO		REFERENCE
1.	SCHEDULING STATUS	As per PPI
2.	S4	
3.	PATIENT INFORMATION LEAFLET	SAHPRA
4.	ROLIXIRD 450 MG (450 mg) film coated tablet	2.14_PIL_Jul
5.	Valganciclovir Hydrochloride	19_v2
6.	(Sugar-free)	As per PPI
7.	Read all of this leaflet carefully before you start taking ROLIXIRD 450 MG	SAHPRA
8.	• Keep this leaflet. You may need to read it again.	2.14_PIL_Jul
9.	• If you have any further questions, ask your doctor or pharmacist.	19_v2
10.	• ROLIXIRD 450 MG has been prescribed for you personally and you	
11.	should not share your medicine with other people. It may harm them,	
12.	even if their symptoms are the same as yours.	
13.		
14.	What is in this leaflet:	SAHPRA
15.	1. What ROLIXIRD 450 MG is and what it is used for.	2.14_PIL_Jul
16.	2. What you need to know before you use ROLIXIRD 450 MG.	19_v2
17.	3. How to use ROLIXIRD 450 MG.	
18.	4. Possible side effects.	
19.	5. How to store ROLIXIRD 450 MG.	
20.	6. Contents of the pack and other information.	
21.		
22.	What ROLIXIRD 450 MG is and what it is used for	In line with
23.	ROLIXIRD 450 MG is indicated for the treatment of cytomegalovirus (CMV)	“Therapeutic
24.	retinitis in acquired immunodeficiency syndrome (AIDS) patients.	Indications” of the

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25.	In the prevention of CMV disease in solid organ transplant patients at risk.	proposed PI (1.3.1.1 Line 22-28)
26.	Valganciclovir is quickly changed in your body to release Ganciclovir, Ganciclovir	
27.	prevents the growth and the increase in numbers of a virus called	
28.	Cytomegalovirus (CMV).	
29.		
30.		
31.	1. What you need to know before you take ROLIXIRD 450 MG	
32.	Do not take ROLIXIRD 450 MG:	In line with “Contraindications” of the proposed PI (1.3.1.1 Line 126-131) As recommended by SAHPRA
33.	• If you have ever had an allergic reaction to valganciclovir, or to ganciclovir, or	
34.	to any of the other ingredients of ROLIXIRD 450 MG.	
35.	• If you have ever had an allergic reaction to aciclovir or valaciclovir.	
36.		
37.	Take special care with ROLIXIRD 450 MG	
38.	• If you have (or have recently had) low numbers of white blood cells, red blood	In line with “Special precautions and warnings for use of the proposed PI” (1.3.1.1 Line 132-198) As recommended by SAHPRA
39.	cells or platelets (small cells involved in blood clotting) in your blood. Your	
40.	doctor will perform blood tests before you start taking ROLIXIRD 450 MG and	
41.	more tests will be done while you are taking ROLIXIRD 450 MG.	
42.	• If you have problems with your kidneys. Your doctor may need to prescribe a	
43.	reduced dose for you and may need to check your blood frequently during	
44.	treatment.	
45.	• If you are on haemodialysis or receiving radiotherapy. ROLIXIRD 450 MG 450	
46.	film-coated tablets are not suitable for people on haemodialysis.	
47.	• If you are currently taking ganciclovir capsules and your doctor wants you to	
48.	switch to ROLIXIRD 450 MG. It is important that you do not take more than	
49.	the dose prescribed by your doctor or you could risk an overdose.	

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50.	<ul style="list-style-type: none"> Safety and efficacy - studies of ROLIXIRD 450 MG use in children are limited. 	
51.		
52.	Taking other medicines with ROLIXIRD 450 MG:	
53.	Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines). See Do not take ROLIXIRD 450 MG.	SAHPRA 2.14_PIL_Jul 19_v2
54.		
55.		
56.	Special care is needed when some other medicines are taken with ROLIXIRD	In line with "Interactions with other medicinal products and other forms of interactions" of the proposed PI (1.3.1.1 Line 199-303) As recommende d by SAHPRA
57.	450 MG, Make sure that you tell your doctor about all the medicines that you are	
58.	taking before you take ROLIXIRD 450 MG, including all medicines that have	
59.	been prescribed for you and any medicines that you have bought without a	
60.	prescription.	
61.	Your doctor may still advise you to take ROLIXIRD 450 MG, but may ask to see	
62.	you more often during treatment and it may be necessary to check your blood	
63.	more often if you are taking the medicines listed below. Taking ROLIXIRD 450	
64.	MG with these medicines may increase the number and severity of any side	
65.	effects.	
66.	Tell your doctor if you are taking or using any of the following medicines:	
67.	If you take Ganciclovir Interactions will be expected for ROLIXIRD 450 MG.	
68.	If you take Imipenem-cilastatin . There may be an increased risk of fits when this	
69.	antibiotic is taken with ROLIXIRD 450 MG.	
69.	If you take Trimethoprim with or without sulphonamides, pentamidine,	
70.	flucytosine, amphotericin B and dapsone taken for the treatment of infections.	
71.	If you take Adriamycin, vincristine, vinblastine and hydroxyurea used in the	
72.	treatment of cancer.	
73.	If you take Zidovudine, didanosine, zalcitabine, stavudine or other medicines	
74.	used in the treatment of HIV. Your doctor may reduce the dose of didanosine that	
75.	you need to take.	

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76.	If you take Probenecid taken for the treatment of gout may increase your blood	
77.	levels of ganciclovir.	
78.	If you take Mycophenolate mofetil , a medicine that is used in patients who have	
79.	received an organ transplant.	
80.	If you take Cidovir, foscarnet, or nucleoside analogues used against viral	
81.	infections.	
82.		
83.	Pregnancy, breastfeeding and fertility	
84.	If you are pregnant or breastfeeding your baby, please consult your	SAHPRA
85.	doctor, pharmacist or other healthcare professional for advice before	2.14_PIL_Jul
87.	ROLIXIRD 450 MG is administered to you.	19_v2
88.	ROLIXIRD 450 MG is not usually given to pregnant woman because it is	In line with
89.	possible that this could lead to the loss of the baby or to the birth of a malformed	“Fertility,
90.	baby or to problems in the baby after birth.	pregnancy
91.		and
92.	Your doctor will only advise you to take ROLIXIRD 450 MG if it is clearly needed	lactation” of
93.	and only after discussing the risks to the unborn baby with you. If you have any	the proposed
94.	questions, ask your doctor.	PI (1.3.1.1
95.	It is also important that both men and women of child-bearing age use	Line 304-323)
96.	effective contraception during treatment with ROLIXIRD 450 MG. If you	As
97.	need advice on contraception, ask your doctor before you start to take	recommende
98.	ROLIXIRD 450 MG. Men should use condoms while taking ROLIXIRD 450 MG	d by
99.	and should continue to use condoms for 90 days after treatment has finished.	SAHPRA
100.	Breastfeeding:	
101.	ROLIXIRD 450 MG must not be used if you are breastfeeding. The active	
102.	ingredient, ganciclovir, may pass into the milk and may harm your baby.	
103.		

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104.	Effects on fertility: No human data on the effect of valganciclovir on fertility are available.	
105.		
107.	Driving and using machines	In line with “Effects on the ability to drive and use machines” of the proposed PI (1.3.1.1 Line 324-329)
108.	No studies on the effects on ability to drive and use machines have been	
109.	performed.	
110.	Adverse reactions such as seizures, dizziness, and confusion have been	
111.	reported with the use of ROLIXIRD 450 MG /or ganciclovir. If they occur, such	
112.	effects may affect tasks requiring alertness, including the patient's ability to drive	
113.	and operate machinery.	
114.		
115.	Important information about some of the ingredients of ROLIXIRD 450 MG	In line with “List of excipients” of the proposed PI and EC Guideline on Excipients in the Labelling and Package Leaflet of Medicinal Products for Human Use Vol 2C, Mar 201
116.	ROLIXIRD 450 MG is Sugar-free.	
117.		
118.		
119.	2. How to take ROLIXIRD 450 MG	
120.	Do not share medicines prescribed for you with any other person.	SAHPRA 2.14_PIL_Jul 19_v2
121.	Always take ROLIXIRD 450 MG exactly as your doctor has instructed	
122.	you. You should check with your doctor or pharmacist if you are unsure.	

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123.	Your doctor will tell you how long your treatment with ROLIXIRD 450 MG will last.	SAHPRA
124.		2.14_PIL_Jul 19_v2
125.	ROLIXIRD 450 MG should be taken with food. If you are unable to eat for any	In line with "Posology and method of administration" of the proposed PI (1.3.1.1 Line 29-124) As recommended by SAHPRA
126.	reason, you should still take the dose when it is due.	
127.	ROLIXIRD 450 MG 450 tablets should be handled with care and should not be	
128.	broken or crushed. You should swallow them whole and with food whenever	
129.	possible.	
130.	If you do accidentally get the Valganciclovir hydrochloride on your skin, eyes or	
131.	touch damaged tablets, wash the area thoroughly with soap and water.	
132.	Your doctor will prescribe an appropriate dose according to your condition.	
133.	It is VERY IMPORTANT that you follow these special dose instructions from your	
134.	doctor.	
135.	Your doctor will tell you how long your treatment with ROLIXIRD 450 MG will last.	
136.	Do not stop treatment early. If you have the impression that the effect of	
137.	ROLIXIRD 450 MG is too strong or weak, tell your doctor or pharmacist.	
138.	Effects when treatment with ROLIXIRD 450 MG 450mg is stopped:	
139.	You must not stop taking ROLIXIRD 450 MG unless your doctor tells you to. If	
140.	you have any further questions on the use of ROLIXIRD 450 MG, ask your	
141.	doctor or pharmacist.	
142.		
143.	Taking ROLIXIRD 450 MG with food and drink	In line with "method of administration" of the proposed PI (1.3.1.1 Line 109-124)
144.	ROLIXIRD 450 MG should be taken with food.	
145.		

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146.	If you take more ROLIXIRD 450 MG than you should	SAHPRA 2.14_PIL_Jul 19_v2
147.	In the event of over dosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison control centre.	
148.		
149.		
150.		
151.	If you missed a dose of ROLIXIRD 450 MG	SAHPRA 2.14_PIL_Jul 19_v2
152.	It is important that you continue to take your medicine according to the	
153.	instructions on the label and that you do not miss any doses. However, if you	
154.	do miss a dose, take it as soon as you remember and take the next dose at the	
155.	normal time. Do not take a double dose to make up for a forgotten dose.	
156.		
157.	3. Possible side effects	
158.	ROLIXIRD 450 MG can have side effects.	SAHPRA 2.14_PIL_Jul 19_v2
159.	Not all side effects reported for ROLIXIRD 450 MG are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ROLIXIRD 450 MG, please consult your doctor, pharmacist or other healthcare professional for advice.	
160.		
161.		
162.		
163.		
164.	If any of the following happens, stop taking ROLIXIRD 450 MG and tell your	SAHPRA 2.14_PIL_Jul 19_v2 In line with "Undesirable effects" of the proposed PI (1.3.1.1 Line 330-348)
165.	doctor immediately or go to the casualty department at your nearest hospital:	
166.	In adults are neutropenia, anaemia and diarrhoea.	
167.	These are all very serious side effects. If you have them, you may have had a	
168.	serious reaction to ROLIXIRD 450 MG . You may need urgent medical attention	
169.	or hospitalisation.	
170.		
171.	Tell your doctor immediately or go to the casualty department at your nearest	In line with "Undesirable effects" of
172.	hospital if you notice any of the following:	

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<p>173. 174. 175. 176. 177. 178. 179. 180. 181. 182. 183. 184. 185. 186. 187. 188. 189. 190. 191. 192. 193. 194. 195. 196. 197. 198. 199.</p>	<p>Allergic reactions Infrequently, people may have a sudden and severe allergic reaction (anaphylactic shock) to ROLIXIRD 450 MG stop taking and go to the nearest hospital emergency room if you experience any of the following:</p> <ul style="list-style-type: none"> • Hives (a raised itchy skin), • Sudden swelling of the throat, face, lips and mouth which may cause difficulty swallowing or breathing, • Sudden swelling of the hands, feet or ankles. <p>These are all very frequent serious side effects. You may need urgent medical attention.</p> <ul style="list-style-type: none"> • Candida infections including oral candidiasis (Infections: fungal infection in the mouth), • Upper respiratory tract infection, • Neutropenia (a reduction in the number of white blood cells in the blood, which will make you more likely to get infections), • Anaemia (a reduction in the pigment in the blood that carries oxygen) which can cause tiredness and breathlessness when you exercise, • Decreased appetite, • Headache, • Cough, • Dyspnoea (feeling short of breath or having trouble breathing), • Diarrhoea, • Nausea, • Vomiting, • Abdominal pain, • Dermatitis (inflamed skin), • Pyrexia (abnormal elevation body temperature), 	<p>the proposed PI (1.3.1.1 Line 349-353)</p>
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200.	• Fatigue (tiredness),	
201.		
202.		
203.	Tell your doctor if you notice any of the following:	<p>In line with “Undesirable effects” of the proposed PI (1.3.1.1 Line 349-353)</p>
204.	Frequent side effects:	
205.	• Sepsis (infections caused by bacteria or viruses in the blood),	
206.	• Influenza (flu),	
207.	• Urinary tract infection,	
208.	• Cellulitis (inflammation of cellular tissue),	
209.	• Thrombocytopenia (a reduction in the number of platelets in the blood),	
210.	• Leukopenia (a reduction in the number of leucocytes) blood cells that fight	
211.	infection in the blood,	
212.	• Pancytopenia (a reduction in several types of blood cells at the same time	
213.	Hypersensitivity),	
214.	• Weight decreased,	
215.	• Depression,	
216.	• Confusional state,	
217.	• Anxiety (restlessness),	
218.	• Insomnia (Inability to sleep),	
219.	• Neuropathy peripheral,	
220.	• Dizziness,	
221.	• Paraesthesia (prickly or tingling skin),	
222.	• Hypoaesthesia (becoming less sensitive to touch),	
223.	• Seizure (convulsions),	
224.	• Dysgeusia (taste disturbance),	
225.	• Visual impairment,	
226.	• Retinal detachment, (Vitreous floaters) spots in the vision,	

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227.	• Eye pain,	
228.	• Conjunctivitis (swollen eyes),	
229.	• Macular oedema (build-up of fluid in the macula),	
230.	• Ear pain,	
231.	• Hypotension (low blood pressure),	
232.	• Dyspepsia (heartburn),	
233.	• Flatulence,	
234.	• Abdominal pain upper,	
235.	• Constipation,	
236.	• Mouth ulceration,	
237.	• Dysphagia (difficulty swallowing),	
238.	• Abdominal distention,	
239.	• Pancreatitis (inflammation of the pancreas),	
240.	• Blood alkaline phosphatase increased,	
241.	• Hepatic function abnormal,	
242.	• Aspartate aminotransferase increased	
243.	• Alanine aminotransferase increased	
244.	• Night sweats,	
245.	• Pruritus (itching),	
246.	• Rash,	
247.	• Alopecia (hair loss),	
248.	• Back pain,	
249.	• Myalgia (pain in the muscles),	
250.	• Arthralgia (pain in the joints),	
251.	• muscle cramps,	
252.	• Renal impairment,	
253.	• Creatinine clearance renal decreased,	

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254.	• Blood creatinine increased,	
255.	• Renal failure,	
256.	• Pain,	
257.	• Chills,	
258.	• Malaise (generally feeling unwell),	
259.	• Asthenia (loss of energy),	
260.		
261.	Less frequent side effects:	<p>In line with “Undesirable effects” of the proposed PI (1.3.1.1 Line 349-353) As recommended by SAHPRA</p>
262.	• Bone marrow failure,	
263.	• Agitation,	
264.	• Psychotic disorder,	
265.	• Thinking abnormal,	
266.	• Hallucinations,	
267.	• Tremor (shaking or trembling),	
268.	• Deafness,	
269.	• Dysrhythmias (irregular heartbeat),	
270.	• Dry skin,	
271.	• Urticaria (itchy rash or swellings),	
272.	• Haematuria (blood in the urine),	
273.	• Infertility male,	
274.	• Chest pain,	
275.	• Aplastic anaemia (body stops producing enough new blood cells),	
276.	• Agranulocytosis (deficiency of granulocytes in the blood),	
277.	• Granulocytopenia (a marked decrease in the number of granulocytes),	
278.	• Anaphylactic reaction,	
279.		

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280.	If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.	SAHPRA 2.14_PIL_Jul 19_v2
281.		
282.		
283.	Reporting of side effects	SAHPRA 2.14_PIL_Jul 19_v2
284.	If you get side effects, talk to your doctor, pharmacist or nurse. This includes any	
285.	possible side effects not listed in this leaflet. You can also report side effects via	
286.	https://www.sahpra.org.za/documents/86422f1b6.04_ARF1_Jul16_v4.pdf . By	
287.	reporting side effects, you can help provide more information on the safety of this	
288.	medicine.	
289.		
290.	4. How to store ROLIXIRD 450 MG	
291.	STORE ALL MEDICINES OUT OF REACH OF CHILDREN.	In line with “Special precautions for storage” of the proposed PI (1.3.1.1 Line 701-705) SAHPRA 2.14_PIL_Jul 19_v2
292.	Store at or below 25 °C.	
293.	Keep in original packaging until required for use.	
294.	Do not store in a bathroom.	
295.	Do not use after the expiry date stated on the label.	
296.	Return all unused medicine to your pharmacist.	
297.	Do not dispose of unused medicine in drains or sewerage systems (e.g.	
298.	toilets).	
299.		
300.		
301.	5. Contents of the pack and other information	
302.	What ROLIXIRD 450 MG contains	In line with “Qualitative and quantitative composition” of the proposed PI
303.	The active substance is Valganciclovir Hydrochloride	
304.	Each film coated tablet contains 496.36 mg of Valganciclovir hydrochloride	
305.	equivalent to 450 mg of valganciclovir.	

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306.	The other ingredients of ROLIXIRD 450 MG are cellulose microcrystalline (PH	(1.3.1.1 Line 9-14 and Line 685-694)
307.	101), cellulose microcrystalline (PH 102), Crospovidone, Povidone, magnesium	
308.	stearate, Opadry pink YS-1-14519A and purified water.	
309.	ROLIXIRD 450 MG Sugar-free.	
310.		
311.	What ROLIXIRD 450 MG looks like and contents of the pack	In line with “Pharmaceutical form” of the proposed PI (1.3.1.1 Line 16-20) In line with “Nature and contents” of the proposed PI (1.3.1.1 Line 707-718)
312.	ROLIXIRD 450 MG 450 mg	
313.	Pink colored, oval shaped biconvex, film-coated tablets, debossed with ‘H’ on	
314.	one side and ‘96’ on other side.	
315.	60 tablets are packed in a Blister strips of 25 µ Polyamide/ 45 µ Aluminium	
317.	foil/ 60 µ PVC film.	
318.	Pack sizes: 10 film coated tablets per blister. One box contains 10 x 6 blisters.	
319.	60 tablets are packed in white opaque round HDPE container closed with a	
320.	white opaque polypropylene continuous thread closures with wad having	
321.	induction sealing liner.	
322.	Pack sizes: 60’s - One HDPE container contains 60 tablets.	
323.	HDPE bottle and blister packs are enclosed in an outer carton box.	
324.		
325.		
326.	NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER	
327.	OF THE CERTIFICATE OF REGISTRATION	
328.	AUROGEN SA (Pty) Ltd	
329.	Woodhill Office Park, Building 1, First Floor	
330.	53 Phillip Engelbrecht Avenue	
331.	Meyersdal, Ext. 12, 1448	
332.	Johannesburg	
333.	South Africa	

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334.		
335.	Registration number 49/20.2.8/0106	