

APPROVED PATIENT INFORMATION LEAFLET

1.	SCHEDULING STATUS
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4.	VILDAGLIPTIN 50 ACCORD
5.	Vildagliptin
6.	Contains: Lactose anhydrous 45.00 mg
7.	
8.	Read all of this leaflet carefully before you take VILDAGLIPTIN 50 ACCORD
9.	<ul style="list-style-type: none"> • Keep this leaflet. You may need to read it again.
10.	<ul style="list-style-type: none"> • If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
11.	
12.	<ul style="list-style-type: none"> • VILDAGLIPTIN 50 ACCORD 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.
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16.	What is in this leaflet
17.	1. What VILDAGLIPTIN 50 ACCORD is and what it is used for
18.	2. What you need to know before you use VILDAGLIPTIN 50 ACCORD
19.	3. How to take VILDAGLIPTIN 50 ACCORD
20.	4. Possible side effects
21.	5. How to store VILDAGLIPTIN 50 ACCORD
22.	6. Contents of the pack and other information
23.	
24.	1. What VILDAGLIPTIN 50 ACCORD is and what it is used for
25.	The active substance of VILDAGLIPTIN 50 ACCORD , vildagliptin, belongs to a group of medicines called "oral antidiabetics".
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27.	VILDAGLIPTIN 50 ACCORD is used to treat adult patients with type 2 diabetes. It is used when
28.	diabetes cannot be controlled by diet and exercise alone. It helps to control the level of sugar in the
29.	blood. Your doctor will prescribe VILDAGLIPTIN 50 ACCORD either alone or together with certain
30.	other antidiabetic medicines which you will already be taking, if these have not proved sufficiently
31.	effective to control diabetes.
32.	
33.	Type 2 diabetes develops if the body does not make enough insulin or if the insulin that the body
34.	makes does not work as well as it should. It can also develop if the body produces too much
35.	glucagon.
36.	
37.	Insulin is a substance which helps to lower the level of sugar in the blood, especially after meals.
38.	Glucagon is a substance which triggers the production of sugar by the liver, causing the blood sugar
39.	level to rise. The pancreas makes both of these substances.
40.	
41.	How VILDAGLIPTIN 50 ACCORD works
42.	VILDAGLIPTIN 50 ACCORD works by making the pancreas produce more insulin and less
43.	glucagon. This helps to control the blood sugar level. This medicine has been shown to reduce blood
44.	sugar, which may help to prevent complications from your diabetes. Even though you are now
45.	starting a medicine for your diabetes, it is important that you continue to follow the diet and/or
46.	exercise which has been recommended for you.
47.	
48.	2. What you need to know before you take VILDAGLIPTIN 50 ACCORD
49.	Do not take VILDAGLIPTIN 50 ACCORD:
50.	<ul style="list-style-type: none">• if you are hypersensitive (allergic) to vildagliptin or any of the other ingredients of
51.	VILDAGLIPTIN 50 ACCORD (listed in section 6).
52.	<ul style="list-style-type: none">• if your liver is not functioning properly

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53.	Warnings and precautions
54.	Talk to your doctor, pharmacist or nurse before taking VILDAGLIPTIN 50 ACCORD
55.	<ul style="list-style-type: none">• if you have type 1 diabetes (i.e. your body does not produce insulin) or if you have a
56.	condition called diabetic ketoacidosis.
57.	<ul style="list-style-type: none">• if you are taking an anti-diabetic medicine known as a sulphonylurea (your doctor may want
58.	to reduce your dose of the sulphonylurea when you take it together with VILDAGLIPTIN 50
59.	ACCORD in order to avoid low blood glucose [hypoglycaemia]).
60.	<ul style="list-style-type: none">• if you have moderate or severe kidney disease (you will need to take a lower dose of
61.	VILDAGLIPTIN 50 ACCORD).
62.	<ul style="list-style-type: none">• if you are on dialysis.
63.	<ul style="list-style-type: none">• if you have liver disease.
64.	<ul style="list-style-type: none">• if you suffer from heart failure.
65.	<ul style="list-style-type: none">• if you have or have had a disease of the pancreas
66.	
67.	If you have previously taken vildagliptin but had to stop taking it because of liver disease, you should
68.	not take this VILDAGLIPTIN 50 ACCORD .
69.	
70.	Diabetic skin lesions are a common complication of diabetes. You are advised to follow the
71.	recommendations for skin and foot care that you are given by your doctor or nurse. You are also
72.	advised to pay particular attention to new onset of blisters or ulcers while taking VILDAGLIPTIN 50
73.	ACCORD . Should these occur, you should promptly consult your doctor.
74.	
75.	A test to determine your liver function will be performed before the start of VILDAGLIPTIN 50
76.	ACCORD treatment, at three-month intervals for the first year and periodically thereafter. This is so
77.	that signs of increased liver enzymes can be detected as early as possible.
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79.	Children and adolescents
80.	The use of VILDAGLIPTIN 50 ACCORD in children and adolescents up to 18 years of age is not
81.	recommended.
82.	
83.	Other medicines and VILDAGLIPTIN 50 ACCORD
84.	Always tell your health care provider if you are taking any other medicine. (This includes all
85.	complementary or traditional medicines).
86.	Your doctor may wish to alter your dose of VILDAGLIPTIN 50 ACCORD if you are taking other
87.	medicines such as:
88.	- thiazides or other diuretics (also called water tablets)
89.	- corticosteroids (generally used to treat inflammation)
90.	- thyroid medicines
91.	- certain medicines affecting the nervous system.
92.	
93.	Pregnancy and breast-feeding
94.	If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby,
95.	please consult your doctor, pharmacist or other health care provider for advice before taking this
96.	medicine.
97.	You should not use VILDAGLIPTIN 50 ACCORD during pregnancy. It is not known if
98.	VILDAGLIPTIN 50 ACCORD passes into breast milk. You should not use VILDAGLIPTIN 50
99.	ACCORD if you are breast-feeding or plan to breast-feed.
100.	
101.	Driving and using machines
102.	VILDAGLIPTIN 50 ACCORD may make you feel dizzy. If you feel dizzy while taking
103.	VILDAGLIPTIN 50 ACCORD , do not drive or use machines.
104.	

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105.	VILDAGLIPTIN 50 ACCORD contains lactose
106.	VILDAGLIPTIN 50 ACCORD contains lactose (milk sugar). If you have been told by your doctor that
107.	you have an intolerance to some sugars, contact your doctor before taking this VILDAGLIPTIN 50
108.	ACCORD .
109.	
110.	3. How to take VILDAGLIPTIN 50 ACCORD
111.	Do not share medicines prescribed for you with any other person.
112.	
113.	Always take VILDAGLIPTIN 50 ACCORD exactly as your doctor or pharmacist has told you. Check
114.	with your doctor or pharmacist if you are not sure.
115.	
116.	How much to take and when
117.	The amount of VILDAGLIPTIN 50 ACCORD people have to take varies depending on their condition.
118.	Your doctor will tell you exactly how many tablets of VILDAGLIPTIN 50 ACCORD to take. The
119.	maximum daily dose is 100 mg.
120.	The usual dose of VILDAGLIPTIN 50 ACCORD is either:
121.	<ul style="list-style-type: none">• 50 mg daily taken as one dose in the morning if you are taking VILDAGLIPTIN 50 ACCORD
122.	with another medicine called a sulphonylurea.
123.	<ul style="list-style-type: none">• 100 mg daily taken as 50 mg in the morning and 50 mg in the evening if you are taking
124.	VILDAGLIPTIN 50 ACCORD alone, with another medicine called metformin or a glitazone,
125.	with a combination of metformin and a sulphonylurea, or with insulin.
126.	<ul style="list-style-type: none">• 50 mg daily in the morning if you have moderate or severe kidney disease or if you are on
127.	dialysis.
128.	
129.	How to take VILDAGLIPTIN 50 ACCORD
130.	<ul style="list-style-type: none">• Swallow the tablets whole with some water.

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131.	How long to take VILDAGLIPTIN 50 ACCORD
132.	<ul style="list-style-type: none">• Take VILDAGLIPTIN 50 ACCORD every day for as long as your doctor tells you. You may
133.	have to take this treatment over a long period of time.
134.	<ul style="list-style-type: none">• Your doctor will regularly monitor your condition to check that the treatment is
135.	having the desired effect.
136.	
137.	If you take more VILDAGLIPTIN 50 ACCORD than you should:
138.	If you take too many VILDAGLIPTIN 50 ACCORD tablets , or if someone else has taken your
139.	medicine, talk to your doctor straight away. In the event of overdosage, consult your doctor or
140.	pharmacist. If neither is available, contact the nearest hospital or poison centre.
141.	
142.	If you forget to take VILDAGLIPTIN 50 ACCORD
143.	If you forget to take a dose of this medicine, take it as soon as you remember. Then take your next
144.	dose at the usual time. If it is almost time for your next dose, skip the dose you missed. Do not take a
145.	double dose to make up for a forgotten tablet.
146.	
147.	If you stop taking VILDAGLIPTIN 50 ACCORD
148.	Do not stop taking VILDAGLIPTIN 50 ACCORD unless your doctor tells you to. If you have questions
149.	about how long to take this medicine, talk to your doctor
150.	
151.	4. Possible side effects
152.	VILDAGLIPTIN 50 ACCORD can have side effects.
153.	Not all side effects for VILDAGLIPTIN 50 ACCORD are included in this leaflet. Should your general
154.	health worsen or if you experience any untoward effects while taking VILDAGLIPTIN 50 ACCORD ,
155.	please consult your doctor, pharmacist or other healthcare professional for advice.
156.	

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157.	Some symptoms need immediate medical attention:
158.	You should stop taking VILDAGLIPTIN 50 ACCORD and see your doctor immediately if you
159.	experience the following side effects:
160.	<ul style="list-style-type: none">• Angioedema: Symptoms include swollen face, tongue or throat, difficulty swallowing,
161.	difficulties breathing, sudden onset rash or hives, which may indicate a reaction called
162.	“angioedema”.
163.	<ul style="list-style-type: none">• Liver disease (hepatitis): Symptoms include yellow skin and eyes, nausea, loss of appetite or
164.	dark-coloured urine, which may indicate liver disease (hepatitis).
165.	<ul style="list-style-type: none">• Inflammation of the pancreas (pancreatitis): Symptoms include severe and persistent pain in
166.	the abdomen (stomach area), which might reach through to your back, as well as nausea
167.	and vomiting.
168.	These are all very serious side effects. If you have them, you may have had a serious reaction
169.	to VILDAGLIPTIN 50 ACCORD. You may need urgent medical attention or hospitalisation.
170.	
171.	Other side effects
172.	Frequent:
173.	<ul style="list-style-type: none">• trembling, headache, dizziness, nausea, low blood glucose
174.	<ul style="list-style-type: none">• weakness
175.	<ul style="list-style-type: none">• weight increase, swollen hands, ankle or feet (oedema)
176.	<ul style="list-style-type: none">• tremor, excessive sweating
177.	<ul style="list-style-type: none">• chills, heartburn
178.	Less frequent:
179.	<ul style="list-style-type: none">• tiredness
180.	<ul style="list-style-type: none">• constipation
181.	<ul style="list-style-type: none">• sore throat, runny nose
182.	<ul style="list-style-type: none">• headache, weakness, low blood glucose

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183.	<ul style="list-style-type: none"> swollen hands, ankle or feet (oedema), joint pain
184.	<ul style="list-style-type: none"> fever
185.	<ul style="list-style-type: none"> diarrhoea, flatulence
186.	Frequency unknown:
187.	<ul style="list-style-type: none"> itchy rash, inflammation of the pancreas, inflammation of the gallbladder, localised peeling of
188.	skin or blisters, muscle pain
189.	
190.	If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.
191.	
192.	Reporting of side effects
193.	If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side
194.	effects not listed in this leaflet. You can also report side effects to SAHPRA via the “ 6.04 Adverse
195.	Drug Reaction Reporting Form ”, found online under SAHPRA’s publications:
196.	https://www.sahpra.org.za/Publications/Index/8 . By reporting side effects, you can help provide more
197.	information on the safety of
198.	VILDAGLIPTIN 50 ACCORD.
199.	
200.	5. How to store VILDAGLIPTIN 50 ACCORD
201.	<ul style="list-style-type: none"> Store at or below 25 °C.
202.	<ul style="list-style-type: none"> Store all medicines out of reach of children.
203.	<ul style="list-style-type: none"> There are no special storage instructions for VILDAGLIPTIN 50 ACCORD
204.	<ul style="list-style-type: none"> Return all unused medicine to your pharmacist.
205.	<ul style="list-style-type: none"> Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
206.	
207.	6. Contents of the pack and other information
208.	What VILDAGLIPTIN 50 ACCORD contains

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209.	<ul style="list-style-type: none">• The active substance is vildagliptin.
210.	<ul style="list-style-type: none">• Each tablet contains 50 mg vildagliptin.
211.	<ul style="list-style-type: none">• The other ingredients are Duralac H (Anhydrous Lactose); magnesium stearate microcrystalline
212.	cellulose (Avicel PH 112); sodium starch Glycolate (Type A)
213.	
214.	What VILDAGLIPTIN 50 ACCORD looks like and contents of the pack
215.	<ul style="list-style-type: none">• White to off-white, round, flat, beveled edge uncoated tablets, debossed with "GF1" and plain on
216.	other side.
217.	<ul style="list-style-type: none">• Dessiflex Alu-Alu blister
218.	<ul style="list-style-type: none">• Pack size: 28 or 56 tablets per carton
219.	<ul style="list-style-type: none">• Not all pack sizes may be marketed.
220.	
221.	HOLDER OF CERTIFICATE OF REGISTRATION
222.	Accord Healthcare (Pty) Ltd
223.	Building 31, Ground Floor,
224.	Woodlands Office Park,
225.	20 Woodlands Drive, Woodmead,
226.	Johannesburg, 2191
227.	Tel: +27 11 234 5701/2
228.	Email: medinfo@accordhealth.co.za
229.	
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231.	23 September 2024
232.	
233.	Registration number
234.	55/21.2/0382

Applicant/HCR: Accord Healthcare (Pty) Ltd
VILDAGLIPTIN 50 ACCORD
Strength: 50 mg vildagliptin

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