

**APPROVED PATIENT INFORMATION LEAFLET**

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**PATIENT INFORMATION LEAFLET**

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**SCHEDULING STATUS:** S4

3

**RINVOQ 15 mg prolonged-release tablets**

4

Upadacitinib

5

Sugar free

6

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

7

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

8

- If you have any further questions, ask your doctor, pharmacist, nurse or other healthcare provider.

9

10

- RINVOQ 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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12

13

**What is in this leaflet**

14

1. What RINVOQ is and what it is used for

15

2. What you need to know before you take RINVOQ

This patient information leaflet has been checked for grammatical and typographical errors.

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- 16           3. How to take RINVOQ  
17           4. Possible side effects  
18           5. How to store RINVOQ  
19           6. Contents of the pack and other information  
20

21           **1. What RINVOQ is and what it is used for**

22 RINVOQ contains the active substance upadacitinib. It belongs to a group of medicines called  
23 Janus kinase inhibitors, which help reduce inflammation.  
24

25 RINVOQ is used to treat adults with rheumatoid arthritis. Rheumatoid arthritis is a disease that  
26 causes inflamed joints. If you have moderate to severe active rheumatoid arthritis, you may first  
27 be given other medicines, one of which will usually be methotrexate. If these medicines do not  
28 work well enough, you will be given RINVOQ either alone or in combination with methotrexate to  
29 treat your rheumatoid arthritis.  
30

31 RINVOQ works by reducing the activity of an enzyme in the body called 'Janus kinase'. By  
32 reducing the activity of this enzyme, RINVOQ can help to reduce pain, stiffness and swelling in  
33 your joints, reduce tiredness and it can slow down damage to the bone and cartilage in your  
34 joints. These effects can ease your normal daily activities and so improve your quality of life.

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### 36 **2. What you need to know before you take RINVOQ**

#### 37 **Do not take RINVOQ**

- 38 • if you are hypersensitive (allergic) to upadacitinib or any of the other ingredients of
- 39 RINVOQ (listed in section 6)
- 40 • if you have a severe infection (such as pneumonia or bacterial skin infection)
- 41 • if you have active tuberculosis (TB)
- 42 • if you have severe liver problems
- 43 • if you are pregnant (see section Pregnancy, breast-feeding and contraception)
- 44 • If you are breastfeeding your baby (see section Pregnancy, breastfeeding and
- 45 contraception)

46

#### 47 **Warnings and precautions**

48 Talk to your doctor or pharmacist before and during treatment with RINVOQ if:

- 49 • you have an infection (fever, sweating, or chills, shortness of breath, warm, red, or
- 50 painful skin or sores on your body, feeling tired, cough, burning sensation when you
- 51 pass urine or passing urine more often than normal, severe headache with stiff neck),

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- 52 or if you have ever had an infection that keeps coming back – RINVOQ can reduce  
53 your body’s ability to fight infections and so may worsen an infection that you already  
54 have, or make it more likely for you to get a new infection
- 55 • you have had tuberculosis or have been in close contact with someone with  
56 tuberculosis. Your doctor will test you for tuberculosis before starting RINVOQ and  
57 may retest during treatment
  - 58 • you have had a herpes zoster infection (shingles), because RINVOQ may allow it to  
59 come back. Tell your doctor if you get a painful skin rash with blisters as these can be  
60 signs of shingles
  - 61 • you have ever had hepatitis B or C
  - 62 • you have recently had or plan to have a vaccination (immunisation) - this is because  
63 live vaccines are not recommended while using RINVOQ
  - 64 • you have cancer - because your doctor will have to decide if you can still be given  
65 RINVOQ
  - 66 • you are at high risk of developing skin cancer, your doctor may recommend preventive  
67 measures such as regular skin examinations while taking RINVOQ. Talk to your doctor  
68 if you develop a new lesion or any change in the appearance of an area on the skin.  
69 Some patients receiving RINVOQ have developed skin cancers
  - 70 • you have heart problems, high blood pressure, or high cholesterol

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- 71       •       your liver does not work as well as it should
- 72       •       you have had blood clots in the veins of your legs (deep vein thrombosis) or lungs
- 73               (pulmonary embolism). Tell your doctor if you get a painful swollen leg, chest pain, or
- 74               shortness of breath as these can be signs of blood clots in the veins.

75

**76    Blood tests**

77    You will need blood tests before you start taking RINVOQ, or while you are taking it. This is to

78    check for a low red blood cell count (anaemia), low white blood cell count (neutropaenia or

79    lymphopaenia), high blood fat (cholesterol) or high levels of liver enzymes. The tests are to check

80    that treatment with RINVOQ is not causing problems.

81

**82    Children and adolescents**

83    RINVOQ is not recommended for use in children and adolescents under 18 years of age. This is

84    because it has not been studied in this age group.

**85    Other medicines and RINVOQ**

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86 Always tell your healthcare provider if you are taking any other medicine. (This includes all  
87 complementary or traditional medicines.) This is because some medicines may reduce how well  
88 RINVOQ works or may increase the risk of getting side effects. It is very important to talk to your  
89 doctor or pharmacist if you are taking any of the following:

- 90 • medicines to treat fungal infections (such as itraconazole, posaconazole or voriconazole)
- 91 • medicines to treat bacterial infections (such as clarithromycin)
- 92 • medicines to treat Cushing's syndrome (such as ketoconazole)
- 93 • medicines to treat tuberculosis (such as rifampicin)
- 94 • medicines to treat seizures or fits (such as phenytoin)
- 95 • medicines that affect your immune system (such as azathioprine, ciclosporin and  
96 tacrolimus)

97

98 If any of the above apply to you or you are not sure, talk to your doctor or pharmacist before  
99 taking RINVOQ.

**100 Pregnancy, breastfeeding and contraception**

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101 If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby,  
102 please consult your doctor, pharmacist or other healthcare provider for advice before taking this  
103 medicine.

104

105 **Pregnancy**

106 RINVOQ must not be used during pregnancy.

107

108 **Breastfeeding**

109 If you are breastfeeding or are planning to breast-feed, talk to your doctor before taking this  
110 medicine. You should not use RINVOQ while breast-feeding. You and your doctor should decide if  
111 you will breast-feed or use RINVOQ. You should not do both.

112

113

114

115 **Contraception**

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116 If you are a woman of child-bearing potential, you must use effective contraception to avoid  
117 becoming pregnant while taking RINVOQ and for at least 4 weeks after your last dose of  
118 RINVOQ. If you become pregnant during this time, you must talk to your doctor straight away.

119

**120 Driving and using machines**

121 RINVOQ has no effect on the ability to drive and use machines.

122

**123 3. How to take RINVOQ**

124 Do not share medicines prescribed for you with any other person.

125 Always take RINVOQ exactly as your doctor or pharmacist has told you. Check with your doctor  
126 or pharmacist if you are not sure.

127 The recommended dose is one 15 mg tablet once a day.

- 128
- Swallow the tablet whole with water. Do not split, crush, chew or break the tablet before  
129 swallowing as it may change how much medicine gets into your body.
  - To help you remember to take RINVOQ, take it at the same time every day.
  - The tablets can be taken with or without food.
- 130
- 131

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- 132
- Do not swallow the desiccant.

133

134 **If you take more RINVOQ than you should**

135 If you take more RINVOQ than you should, contact your doctor. You may get some of the side  
136 effects listed in section 4.

137 In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the  
138 nearest hospital or poison centre.

139

140 **If you forget to take RINVOQ**

- 141
- If you miss a dose, take it as soon as you remember.
- 142
- If you forget your dose for an entire day, just skip the missed dose and take only a single  
143 dose as usual the following day.
- 144
- Do not take a double dose to make up for a forgotten tablet.

145

146 **If you stop taking RINVOQ**

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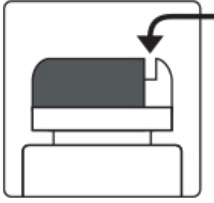
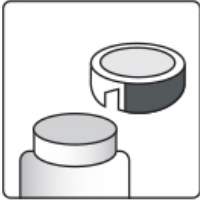
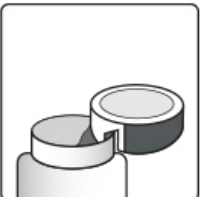
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147 Do not stop taking RINVOQ unless your doctor tells you to stop taking it.

148

149 **How to open the bottle**


|   |   |
|---|---|
|    | <p><b>Foil Cutting Tool</b> - on the cap of the bottle</p>  |
|  | <p><b>1. How to puncture the foil</b></p> <p><b>1a.</b> Remove the cap from the bottle by pushing down and while still pushing, turn the cap anti-clockwise.</p> <p><b>1b.</b> Turn the cap over and place the cutting tool near the edge of the foil seal.</p> |
|  | <p><b>2.</b> Push down to make a hole in the foil and move the cutting tool round the</p>   |

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|   |  |
|---|--|
|   | edge of the foil to continue cutting the foil.                                       |
|  | <b>3.</b> When you have taken your tablet, put the cap back on and close the bottle. |

150

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

152

153 **4. Possible side effects**

154 RINVOQ can have side effects.

155 Not all side effects reported for RINVOQ are included in this leaflet. Should your general health

156 worsen or if you experience any untoward effects while taking RINVOQ, please consult your

157 healthcare provider for advice.

158 **Serious side effects**

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159 Talk to your doctor or get medical help straight away if you get any signs of infection such as:

- 160 • shingles or painful skin rash with blisters (herpes zoster)
- 161 • infection of the lung (pneumonia), which may cause shortness of breath, fever, and a
- 162 cough with mucus

163

164 **Other side effects**

165 Talk to your doctor if you notice any of the following side effects:

166 **Frequent**

- 167 • throat and nose infections
- 168 • cough
- 169 • fever
- 170 • feeling sick in the stomach (nausea)
- 171 • increase in an enzyme called creatine kinase, shown by blood tests
- 172 • low white blood cell counts shown in blood tests
- 173 • increased levels of cholesterol (a type of fat in the blood) as shown in tests
- 174 • increased levels of liver enzymes, shown by blood tests (sign of liver problems)
- 175 • weight gain

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176

177 **Less frequent**

- 178 • cold sores (herpes simplex)
- 179 • thrush in the mouth (white patches in the mouth)
- 180 • increased levels of triglycerides (a type of fat in the blood) as shown in tests

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

183

184 **Reporting of side effects**

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

189

190 **5. How to store RINVOQ**

191 Store all medicines out of reach of children.

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192 Do not use this medicine after the expiry date which is stated on the blister label and carton after  
193 'EXP'.

194 Store RINVOQ at or below 25 °C

195 Store in original blister or bottle with the lid tightly closed to protect from moisture.

196 Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how  
197 to throw away medicines you no longer use. These measures will help protect the environment.

198

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

200 **What RINVOQ contains**

- 201 • The active substance is upadacitinib. Each prolonged-release tablet contains 15 mg of  
202 upadacitinib (as upadacitinib hemihydrate).
- 203 • The other ingredients are:
- 204 • Core tablet: microcrystalline cellulose, mannitol, tartaric acid, hypromellose, silica colloidal  
205 anhydrous, magnesium stearate.
- 206 • Film coating: poly(vinyl alcohol), macrogol, talc, titanium dioxide, iron oxide red (E172),  
207 iron oxide black (E172).

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**209 What RINVOQ looks like and contents of the pack**

210 RINVOQ 15 mg prolonged-release tablets are purple, oblong, biconvex tablets imprinted on one  
211 side with 'a15'.

212 The tablets are provided in blisters or bottles.

213 The calendar blister packaging is composed of polyvinylchloride /polyethylene  
214 /polychlorotrifluoroethylene /aluminium

215 RINVOQ is available in packs containing 28 or 98 prolonged-release tablets and in multipacks of  
216 84 comprising 3 cartons, each containing 28 prolonged-release tablets.

217 Each calendar blister contains 7 tablets.

218

219 The bottle is composed of high-density polyethylene (HDPE) with desiccant and a polypropylene  
220 cap

221 RINVOQ is available in bottles with desiccant in a carton containing 30 prolonged-release tablets,  
222 each pack contains 1 bottle (30 tablet pack) or 3 bottles (90 tablet pack).

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223 Not all pack sizes may be marketed.

224

225 **Holder of Certificate of Registration**

226 AbbVie (Pty) Ltd

227 Abbott Place, 219 Golf Club Terrace

228 1709, Constantia Kloof

229 Republic of South Africa

230 Tel No: (011) 831 3200

231

232 **This leaflet was last revised in**

233 06 April 2022

234

235 **Registration number**

236 54/3.1/0187

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237 **Access to the corresponding Professional Information**

238 For the professional information please email [medicalinfo.za@abbvie.com](mailto:medicalinfo.za@abbvie.com)

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