

1 **ZOVIRAX ORAL RANGE**
2 **Approved Patient Information Leaflet**
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Read all of this leaflet carefully before you start taking ZOVIRAX.

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

If you have further questions, please ask your doctor or your pharmacist.

ZOVIRAX has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

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7 **SCHEDULING STATUS:**

8 **S4**
9

10 **PROPRIETARY NAMES AND DOSAGE FORMS:**

11 **ZOVIRAX 200** Dispersible Tablets

12 **ZOVIRAX SUSPENSION**
13

14 **COMPOSITION OF ZOVIRAX, THAT IS, WHAT ZOVIRAX CONTAINS:**

15 Each ZOVIRAX 200 dispersible tablet contains 200 mg acyclovir.

16 The inactive ingredients include microcrystalline cellulose, aluminium magnesium silicate,
17 sodium starch glycollate, povidone K30 and magnesium stearate. The film coat contains
18 hypromellose, titanium dioxide and polyethylene glycol.
19

20 Each 5 ml of ZOVIRAX SUSPENSION contains 200 mg acyclovir, methyl hydroxy benzoate
21 0,1 % *m/v* and propyl hydroxybenzoate 0,02 % *m/v* (as preservatives).

22 The inactive ingredients include sorbitol, glycerol, Avicel, vanillin, banana flavourant and
23 purified water.

24

25 **APPROVED INDICATION AND USE, THAT IS, WHAT ZOVIRAX IS USED FOR:**

26 Acyclovir (the active ingredient of ZOVIRAX) belongs to a group of medicines called anti-
27 virals. ZOVIRAX works by stopping the production of the virus.

28 This reduces the length and severity of an outbreak of infection. ZOVIRAX does not get rid
29 of the virus from your body.

30 ZOVIRAX is used to treat *herpes simplex* infections of the skin and mucous membranes
31 including initial and recurrent genital herpes.

32 ZOVIRAX may also be used to treat shingles and chickenpox.

33

34 Your doctor may sometimes prescribe ZOVIRAX for other purposes, or at different doses to
35 those stated below:

- 36 • in patients with advanced HIV disease, to reduce the risk of developing herpes
37 infections. In this case, ZOVIRAX must be taken in conjunction with antiretrovirals
38 (medicines used to treat HIV infections)
- 39 • following bone marrow transplant. In this case, oral ZOVIRAX can only be given
40 following one month treatment with intravenous ZOVIRAX.

41

42 **INSTRUCTIONS BEFORE TAKING ZOVIRAX:**

43 **Do not use ZOVIRAX if:**

- 44 • you have an allergy to this medicine, acyclovir, valaciclovir or to any of the inactive
45 ingredients.

46

47 **Before you start taking your medicine, tell your doctor if:**

- 48 • you are pregnant or intend to become pregnant
- 49 • you are breastfeeding or planning to breastfeed
- 50 • you have a kidney or liver condition
- 51 • if you are elderly
- 52 • if you are taking any of the following medicines: probenecid, cimetidine or
- 53 mycophenolate (immunosuppressant agent used in kidney transplants).

54 If you answer yes to any of the above questions, or if you are unsure if they apply to you,
55 and if you have not already discussed with your doctor, tell your doctor or pharmacist before
56 you start taking ZOVIRAX.

57 Always tell your health care professional if you are taking any other medicine.

58 If you are pregnant or breast feeding your baby please consult your doctor, pharmacist or
59 other health care professional for advice before taking this medicine.

60

61 **INSTRUCTIONS ON HOW TO TAKE ZOVIRAX:**

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

63 It is important that you or your child take ZOVIRAX at the right times, in the way that your
64 doctor has told you. The label on your pack will tell you how much, how often, and for how
65 long to take your medicine. If the label does not say, or if you are not sure, ask your doctor
66 or pharmacist.

67 If you are elderly or if you have kidney problems, the doctor may adjust your dosage. Your
68 doctor will be monitoring you closely as there is a risk of you experiencing nervous system
69 side effects (see SIDE EFFECTS).

70 It is important that you drink adequate fluids whilst you are having treatment.

71

72 **Adults:**

73 ***Treatment of current and recurrent herpes simplex infections of the skin and mucous***
74 ***membranes:***

75 The usual adult dosage is 200 mg five times per day, at four hourly intervals, for 5 days.

76 Some patients take 400 mg five times a day, at four hourly intervals.

77 For more severe infections your doctor may prescribe this medicine for longer than 5 days.

78

79 ***Suppression of recurrent genital herpes infections:***

80 The usual adult dosage is 200 mg four times per day, at six hourly intervals.

81 Some patients may be treated with 400 mg twice daily at 12-hourly intervals, or 200 mg
82 three times a day at 8-hourly intervals.

83 Treatment may continue for up to 6 months, with regular visits to your doctor to determine
84 how well your treatment is working and the progression of your infection.

85

86 ***Prevention of current attacks of herpes simplex infections:***

87 If you have been given ZOVIRAX to stop you becoming infected with *herpes simplex*, the
88 usual adult dosage is 200 mg to 400 mg four times per day at six hourly intervals.

89 Duration of treatment will depend on the time period that you may be at risk from contracting
90 the herpes infection.

91

92 ***Treatment of chickenpox or shingles:***

93 The usual adult dose is 800 mg five times per day at four hourly intervals, for 7 days.

94

95 **Children:**

96 Children over two years should be given the same dosages as adults.

97 Children under two years should be given half the adult dose.

98 The doctor may also prescribe a dose for your child according to your child's bodyweight.

99

100 ***If you miss a dose:***

101 If you forget to take a dose don't worry. Just take one dose as soon as you remember and
102 then take the next dose at the correct time.

103

104 ***If you take too much:***

105 In the event of over dosage, consult your doctor or pharmacist. If neither is available,
106 contact the nearest hospital or poison control centre.

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108 **SIDE EFFECTS:**

109 Some people may experience side effects with ZOVIRAX. Tell your doctor if you experience
110 any of the following side effects:

111

112 The most common side effects include:

- 113 • headache, dizziness
- 114 • feeling or being sick (nausea, vomiting), diarrhoea and stomach cramps
- 115 • itching, skin rashes (including a skin reaction after exposure to sunlight)
- 116 • fever and feeling tired.

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118

119 Uncommon side effects include:

120 • mild skin reactions e.g. hives/nettle rash

121 • hair loss.

122

123 Rare side effects include:

124 • severe allergic reaction symptoms which include, sudden wheeziness, fluttering or
125 tightness in the chest, collapse, swelling of eyelids, face, lips or elsewhere, skin rash or

126 weals. Check with your doctor immediately if you or your child experience any of these

127 severe symptoms. **These symptoms may mean that you or your child, are allergic**

128 **to ZOVIRAX.** Do NOT take any more of this medicine unless your doctor has advised

129 you to do so

130 • difficulty breathing

131 • effects on some blood and urine tests. Let the doctor know that you are taking ZOVIRAX

132 if you are having a blood or urine test.

133

134 Very rare side effects include:

135 • liver problems, or yellowing of the skin and the whites of the eyes

136 • impaired kidney function or kidney failure

137 • weakness, tiredness, feeling faint or shortness of breath. These symptoms may mean

138 you have reduced number of red blood cells (anaemia)

139 • although you may not notice any symptoms, this medicine may cause a decrease in your

140 white blood cells

141 • bruising or nose bleeds. These symptoms mean you have a low number of platelets, a

142 type of white blood cell

- 143 • agitation, confusion, shakiness, irregular body movements, difficulties with speech,
144 hallucinations, fits, drowsiness, sleepiness during the day, loss of contact with reality.

145 If you or your child suffer from any of the above side effects which are causing you concern,
146 or if you notice any other side effect that is not listed above, tell your doctor or pharmacist.

147 Not all side effects reported for this medicine are included in this leaflet. Should your
148 general health worsen or if you experience any untoward effects while taking this medicine,
149 please consult your doctor, pharmacist or other health care professional for advice.

150

151 **STORAGE AND DISPOSAL INFORMATION:**

152 Store all medicines out of reach of children.

153 Protect from light.

154 ZOVIRAX 200 Dispersible Tablets: Store below 30 °C and in dry place.

155 ZOVIRAX SUSPENSION: Store below 25 °C.

156 Do not use if the expiry date on the packaging has passed. If you take this medicine after
157 the expiry date has passed, it may not work as well.

158

159 **PRESENTATION:**

160 ZOVIRAX 200 Dispersible Tablets: Blister packs of 25 tablets.

161 ZOVIRAX SUSPENSION: Amber glass bottles closed with polypropylene child resistant
162 (CR) caps fitted with a reseal line and Low Density Polyethylene (LDPE) tamper-evident
163 ring. The reseal liner is an Expanded Polyethylene (EPE) core faced with Polyethylene-
164 Polyvinylidene Chloride-Polyethylene (PE-PVDC-PE) cover film on both sides.

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166 **IDENTIFICATION:**

167 ZOVIRAX 200 Dispersible Tablets: White, round, biconvex, film-coated tablets, branded
168 'GXCF3' on one side and plain on the other side.
169 ZOVIRAX SUSPENSION: An off-white, viscous suspension with a banana odour and taste.

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171 **REGISTRATION NUMBERS:**

172 ZOVIRAX 200 Dispersible Tablets: 29/20.2.8/0452

173 ZOVIRAX SUSPENSION: S/20.2.8/236

174

175 **NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF**

176 **REGISTRATION:**

177 GlaxoSmithKline South Africa (Pty) Ltd

178 39 Hawkins Avenue, Epping Industria 1, 7460

179

180 **DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:**

181 Date of last approval: 15 April 2011

182 Date compliant with Regulation 9: 26 March 2015

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