

1 **ZOVIRAX® CREAM**

2 **SCHEDULING STATUS:**

3 **S4**

4

5 **PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:**

6 **ZOVIRAX CREAM**

7 **Acyclovir**

8

Read all of this leaflet carefully before you start using ZOVIRAX CREAM.

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

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

ZOVIRAX CREAM 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.

9

10 **WHAT ZOVIRAX CREAM CONTAINS:**

11 1 gram of cream contains 0,05 grams of acyclovir.

12 The inactive ingredients include poloxamer 407, cetostearyl alcohol, sodium lauryl
13 sulphate, white soft paraffin, liquid paraffin, propylene glycol and purified water.

14

15 **WHAT ZOVIRAX CREAM IS USED FOR:**

16 ZOVIRAX contains the active ingredient acyclovir. Acyclovir belongs to a group of
17 medicines called antivirals, used for treating infections caused by the herpes simplex
18 virus.

20 ZOVIRAX CREAM is used to treat cold sores, genital herpes and other skin infections
21 caused by the herpes simplex virus. It is not for use in your eyes, or inside your mouth
22 or vagina.

23

24 **BEFORE YOU USE ZOVIRAX CREAM:**

25 **Do not use ZOVIRAX CREAM:**

- 26 • if you are hypersensitive (allergic) to acyclovir, valacyclovir, propylene glycol, or any
27 of the ingredients of ZOVIRAX CREAM
- 28 • for herpes infections of the eyes or genital area.

29

30 **Take special care with ZOVIRAX CREAM:**

- 31 • if you are pregnant or intend to become pregnant
- 32 • if you are breastfeeding or planning to breastfeed
- 33 • if you are under the care of a doctor because of a weak immune system (i.e. your
34 ability to fight infection is reduced) e.g. HIV infection, a bone marrow transplant or
35 cancer treatment. If so, a skin infection could be more serious for you than with other
36 people.

37

38 Tell your doctor each time you get a cold sore or herpes blister. Do not treat it yourself
39 with ZOVIRAX CREAM, unless your doctor tells you to.

40 Only use the ZOVIRAX CREAM on cold sores on your face and anywhere on the skin.

41 Avoid contact with your eyes.

42 Do not use cream inside your mouth, or vagina.

43 If you are in any doubt whether your sore is a cold sore, consult your doctor. If your cold
44 sore is, or becomes, very severe you should consult your doctor.

45

46 **Pregnancy and Breastfeeding:**

47 If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist
48 or other healthcare professional for advice before using ZOVIRAX CREAM.

49

50 **Using other medicines with ZOVIRAX CREAM:**

51 Always tell your healthcare professional if you are taking any other medicine. (This
52 includes complementary or traditional medicines.)

53 ZOVIRAX CREAM is unlikely to interact with other medicines you are being treated with.

54

55 **HOW TO USE ZOVIRAX CREAM:**

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

57 Always wash your hands before and after you use the cream.

58 ZOVIRAX CREAM works best if you start using it as early as possible. If it is your first
59 herpes infection, start using the cream straight away. If you get herpes blisters regularly
60 start using the cream as soon as you feel one starting to come up. You may feel a
61 tingling or itching sensation as this happens.

62

63 **Please follow these instructions carefully:**

64 **Adults and children:**

- 65 1. Wash your hands thoroughly before and after treating the sores so as to avoid
66 making it worse, or giving the infection to someone else.
- 67 2. Apply a thin layer of cream to the whole of the affected area.
- 68 3. Apply to affected area **5 times daily** about every four hours. If you forget a
69 treatment apply some as soon as you remember, then continue as before.

70 4. Continue treatment for four days. If your sore has not healed after this time,
71 treatment may be continued for a further 5 days. If full healing has not occurred
72 after 10 days, or if your cold sore becomes very severe, stop the cream and
73 consult your doctor.

74 5. Do not mix ZOVIRAX CREAM with any other skin cream or lotion.
75

76 **Remember:**

77 1. Do not use the cream inside your eyes. If you get any of the cream inside your
78 eyes, wash it out with plenty of cool water. If your eyes get sore afterwards, tell
79 your doctor.

80 2. Do not use the cream inside your mouth or vagina. It may irritate the skin in
81 these areas.
82

83 **If you use more ZOVIRAX CREAM than you should:**

84 If you use more ZOVIRAX CREAM than you should have, tell your doctor or pharmacist,
85 taking the packaging with you to show them.

86 However, if you think that someone has accidentally swallowed the cream, consult your
87 doctor or pharmacist. If neither is available, contact the nearest hospital or poison
88 control centre.
89

90 **If you forget to use ZOVIRAC CREAM:**

91 If you forget to apply your cream, do not worry. Make an application as soon as you
92 remember, then carry on as before. Do not apply twice as much cream to make up for
93 forgotten individual doses.
94

95 **POSSIBLE SIDE EFFECTS:**

96 ZOVIRAX CREAM can have side effects.

97 Not all side effects reported for ZOVIRAX CREAM are included in this leaflet. Should
98 your general health worsen or if you experience any untoward effects while taking this
99 medicine, please consult your doctor, pharmacist or other healthcare professional for
100 advice.

101 Some people may get the following:

- 102 • A mild burning or stinging may sometimes occur when you first put it on.
- 103 • Occasionally redness, itching or a mild drying or flaking of the skin may occur.
- 104 • Inflammation of sensitivity reactions may develop, usually due to the inactive
105 ingredients of the cream.
- 106 • Rarely an allergic reaction may develop. Symptoms include swelling, especially
107 of the lips, face and/or eyelids, skin rashes and weals. If you experience an
108 allergic reaction with ZOVIRAX CREAM, stop using the cream and contact your
109 doctor immediately.

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111 If in doubt, or if these side effects become troublesome, stop the treatment and consult
112 your doctor or pharmacist.

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

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116 **STORING AND DISPOSING OF ZOVIRAX CREAM:**

117 Store all medicines out of reach of children.

118 Store below 25 °C.

119 Do not refrigerate.

120 Do not use if the expiry date on the packaging has passed.

121

122 **PRESENTATION:**

123 ZOVIRAX CREAM may be packaged in the following:

124 Collapsible aluminium tube of nominal fill 2 g, with membrane seal, internally lacquered with
125 a plastic screw cap.

126 Collapsible aluminium tube of nominal fill 10 g, with membrane seal, internally lacquered with a
127 plastic screw cap.

128 2 g Pump Dispenser: Polypropylene container (bottle) of nominal fill 2 g with a pump
129 assembly and polypropylene cap

130

131 **IDENTIFICATION:**

132 ZOVIRAX CREAM is white to off white.

133

134 **REGISTRATION NUMBER:**

135 R/20.2.8/271

136

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

138 **REGISTRATION:**

139 GlaxoSmithKline South Africa (Pty) Ltd

140 39 Hawkins Avenue

141 Epping Industria 1, 7460

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

144 Date of last approval: 23 July 2010

145 Date compliant with Regulation 10: 25 August 2016

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