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## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS:

The scheduling status if ADVIL COLD and SINUS is Schedule 2 (S2).

### PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

The name of your medicine is **ADVIL COLD and SINUS**.

ADVIL COLD and SINUS is available in a tablet dosage form. The ADVIL COLD and SINUS tablets contain the two active ingredients ibuprofen and pseudoephedrine hydrochloride.

### Read all of this leaflet carefully because it contains important information for you.

ADVIL COLD and SINUS is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use ADVIL COLD and SINUS tablets carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ADVIL COLD and SINUS with any other person.
- Ask your pharmacist if you need more information or advice.
- Contact your doctor if your symptoms worsen or do not improve after 7 days for treatment of a cold and after 3 days for treatment of a fever.

### WHAT ADVIL COLD and SINUS CONTAIN:

Each tablet contains the following active ingredients:

- |                               |        |
|-------------------------------|--------|
| Ibuprofen                     | 200 mg |
| Pseudoephedrine hydrochloride | 30 mg. |

The tablets also contain the inactive ingredient excipients: Anhydrous colloidal silica, black printing ink, butterscotch colouring agent (iron oxide red, iron oxide yellow, titanium

28 dioxide), carnauba wax, croscarmellose sodium, maize starch, methyl  
29 parahydroxybenzoate, microcrystalline cellulose, opaglos, povidone, pregelatinised  
30 starch, propyl parahydroxybenzoate, sodium lauryl sulphate, stearic acid and sucrose.

31

### 32 **WHAT ADVIL COLD and SINUS IS USED FOR:**

33 ADVIL COLD and SINUS tablets are used for the relief of symptoms associated with the  
34 common cold, sinusitis, or flu, such as blocked nose, headache, fever, body aches and  
35 pain.

36 The active substance ibuprofen belongs to a group of medicines called nonsteroidal anti-  
37 inflammatory drugs (known as NSAIDs), which reduce fever and relieve pain.

38 The other active substance pseudoephedrine hydrochloride is a decongestant, which  
39 relieves nasal congestion.

40

### 41 **BEFORE YOU TAKE ADVIL COLD and SINUS:**

#### 42 **Do NOT take ADVIL COLD and SINUS if:**

- 43 • you are allergic to ibuprofen, any other nonsteroidal anti-inflammatory medicine,  
44 aspirin or any other pain or fever relieving medicine
- 45 • you are allergic to pseudoephedrine hydrochloride
- 46 • you are allergic to any other ingredient contained within the tablets (see “What  
47 ADVIL COLD and SINUS contains”)
- 48 • you have had or are suffering from asthma, recurrent ulcers or bleeding ulcers,  
49 any bleeding disorder, heart failure or any heart or blood pressure disorder, a liver  
50 disorder or a kidney disorder
- 51 • you have had or are suffering from prostatic hypertrophy (enlargement of the  
52 prostate gland), overactive thyroid, diabetes mellitus (sugar diabetes), glaucoma  
53 (an eye disease)
- 54 • you are pregnant or breast-feeding (see “**Pregnancy and Breast-feeding**”)

- 55       • you are taking a prescription monoamine oxidase inhibitor (medicine prescribed  
56           for depression, psychiatric or emotional conditions or Parkinson’s disease) or if it  
57           has been less than 14 days since you have stopped treatment with a monoamine  
58           oxidase inhibitor (MAOI).

59    ADVIL COLD and SINUS must not be given to children under 12 years.

60    **Take special care with ADVIL COLD and SINUS:**

- 61       • If you have trouble sleeping, take the last dose for each day several hours before  
62           bedtime.
- 63       • Do not drink alcoholic beverages while taking ADVIL COLD and SINUS, as  
64           stomach problems may be more likely to occur if you drink alcoholic beverages.
- 65       • The risk of gastrointestinal bleeding or ulceration is higher with increasing doses,  
66           in patients with a history of ulcers and the elderly.
- 67       • Serious skin reactions have been reported in association with NSAID therapy.  
68           Discontinue treatment at the first appearance of rash or any other sign of  
69           hypersensitivity and contact your doctor.

70

71    **Ask your doctor or pharmacist for advice before taking ADVIL COLD and SINUS**  
72    **tablets if:**

- 73       • you are older than 65 years.
- 74       • you are allergic to any other pain or fever relieving medicines, such as aspirin or  
75           other NSAIDs (see “**Do not take ADVIL COLD and SINUS if**”).

76

77    **Ask your doctor or pharmacist for advice before taking ADVIL COLD and SINUS**  
78    **tablets if you have suffered or suffer from any other medical problem, or if you are**  
79    **under a doctor’s care for any continuing medical condition, for example:**

- 80       ♦ asthma, high blood pressure, heart failure or heart disease, fluid retention, hepatitis  
81           or other liver disease, kidney disease, diabetes mellitus (sugar diabetes)

- 82 ♦ stomach or colon irritation or bleeding, colitis, Crohn's disease, diverticulitis, stomach  
83 ulcer or other stomach or intestinal problems
- 84 ♦ epilepsy, anaemia, systemic lupus erythematosus (SLE)
- 85 ♦ bleeding problems.

86

87 **Pregnancy and Breast-feeding:**

88 The ADVIL COLD and SINUS tablets are not recommended for use in pregnant or  
89 breast-feeding women.

90 If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or  
91 other healthcare professional for advice before taking this medicine.

92

93 **Important information about some of the ingredients of ADVIL COLD and SINUS**  
94 **tablets:**

95 The ADVIL COLD and SINUS tablets are sugar-coated tablets. The sugar-coating of  
96 these tablets contains sugar (sucrose).

97

98 **Taking other medicine with ADVIL COLD and SINUS**

99 Always tell your healthcare professional before taking ADVIL COLD and SINUS tablets if  
100 you are taking any other medicine on a regular basis, this includes complimentary,  
101 prescription, non-prescription or traditional medicines. Examples of medicines that may  
102 interact with ADVIL COLD and SINUS tablets include:

- 103 ♦ medicines to reduce the clotting of the blood
- 104 ♦ medicines to treat diabetes.
- 105 ♦ medicines to reduce your blood pressure or medicines to stimulate the heart.
- 106 ♦ lithium, methotrexate, corticosteroids, diuretics, quinolones, selective serotonin  
107 reuptake inhibitors (a class of antidepressant), alcohol, phenytoin, beta blockers,  
108 insulin, oral antidiabetic agents, antiplatelets such as clopidogrel and ticlopidine

- 109 ♦ aspirin, any other product that contains ibuprofen or any other pain or fever relieving
- 110 medicine
- 111 ♦ central nervous system stimulation-producing agents, levodopa, quinidine, tricyclic
- 112 antidepressants, halogenated anaesthetics, digitalis, thyroid hormones, citrates,
- 113 nitrates.
- 114 ♦ monoamine oxidase inhibitors (see “**Do not take ADVIL COLD and SINUS tablets**
- 115 **if:”**)
- 116 ♦ any other medicine that contains pseudoephedrine hydrochloride or any other
- 117 decongestant.

118

#### 119 **HOW TO TAKE ADVIL COLD and SINUS:**

##### 120 **Adults and children 12 years and older:**

121 Take one tablet every 4 to 6 hours. If symptoms do not respond to one tablet, a second  
122 tablet may be taken.

123 Do not take more than 6 tablets in any 24-hour period.

124 ADVIL COLD and SINUS should be taken with a glass of water, with food or after meals.

125 Do not take for a cold for more than 7 days or for fever for more than 3 days, unless  
126 directed by a doctor.

127 If the cold or fever persists or gets worse, or if new symptoms occur, consult a doctor.

128 Use the lowest effective dose for the shortest possible duration of treatment.

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

130 For safe and effective use of ADVIL COLD and SINUS, do not take more of it, do not  
131 take it more often, and do not take it for a longer time than ordered by your health care  
132 professional or as directed on the package label.

133

##### 134 **If you take more ADVIL COLD and SINUS than you should:**

135 In case of accidental overdose, immediately consult your doctor or pharmacist. If neither  
136 is available, immediately contact the nearest hospital or poison control centre.

137

138 **If you forget to take ADVIL COLD and SINUS:**

139 Do not take double doses to make up for forgotten individual doses.. Continue taking the  
140 tablets as directed on the label.

141 Contact your healthcare professional for further advice.

142

143 **POSSIBLE SIDE-EFFECTS:**

144 ADVIL Cold & Sinus can have side effects.

145 **Stop taking ADVIL COLD and SINUS and get medical assistance right away if any**  
146 **of the following side-effects occur:** fainting, facial swelling, fast or irregular breathing;  
147 shortness of breath, chest pain, wheezing or tightness in chest; fast or irregular heartbeat  
148 or pulse; unusual flushing or warmth of the skin; hive-like swellings on face, eyelids,  
149 mouth, lips or tongue; puffiness or swelling of eyelids.

150

151 **Stop taking ADVIL COLD and SINUS and check with your doctor immediately if any**  
152 **of the following side-effects occur:** abdominal or stomach pain, cramping or burning;  
153 bloody or black stools; chest pain, convulsions (seizures), fever with or without chills;  
154 severe or continuing nausea or heartburn or indigestion; sores or ulcers on lips or mouth;  
155 unexplained nosebleeds; unusual bleeding or bruising; spitting up blood; vomiting of  
156 blood or material that looks like coffee grounds; skin rash; hallucinations.

157

158 **Also, check with your doctor as soon as possible if any of the following side-**  
159 **effects occur:** bladder pain; bloody or cloudy urine; any problem with urination; blurred  
160 vision or any change in vision; ringing or buzzing in ears; bleeding from cuts and

161 scratches that lasts longer than usual; severe headache; burning feeling in the throat,  
162 chest or stomach; mood or mental changes; unusual tiredness; yellow eyes or skin.

163

164 **Other side-effects may occur. However, check with your doctor if any of the**  
165 **following side-effects continue or are bothersome:**

166 general feeling of discomfort or illness, dizziness, lightheadedness, heartburn,  
167 indigestion, nausea, bloated feeling, sensitivity to light (eyes or skin); trouble sleeping,  
168 nervousness, restlessness.

169

170 **Not all side effects reported for ADVIL COLD and SINUS are included in this leaflet.**  
171 **If your general state of health worsens or if you experience any untoward effects**  
172 **while taking ADVIL COLD and SINUS, please consult your doctor, pharmacist or**  
173 **other healthcare professional for advice..**

174

175 **STORING AND DISPOSING OF ADVIL COLD and SINUS:**

176 Store at or below 25 °C. Protect from light and exposure to air.

177 Store in the original package.

178 Do not use this medicine after the expiry date shown on the carton.

179 STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

180 Return all unused medicine to your pharmacist.

181 Do not dispose of unused medicine in drains or sewerage systems (e.g.toilets).

182

183 **PRESENTATION OF ADVIL COLD and SINUS:**

184 Cartons containing blister packs of 10 or 20 tablets per carton.

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186 **IDENTIFICATION OF ADVIL COLD and SINUS:**

187 A butterscotch coloured, oval-shaped, sugar-coated tablet with a polished surface and

188 “Advil Cold and Sinus” printed on one side

189

190 **REGISTRATION NUMBER:**

191 Z/5.8/248.

192

193 **NAME AND BUSINESS ADDRESS OF THE REGISTRATION HOLDER:**

194 Pfizer Laboratories PFE (Pty) Ltd

195

196 85 Bute Lane

197 Sandton, 2191

198 2191

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200 **DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET:**

201 20 April 2012

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203

Botswana Reg. No.:	0400687
Schedule	: 3
Namibia Reg. No.:	04/5.8/1008
Schedule	: NS0

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