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MEDICATION GUIDE
ACCUTANE® (ACK-u-tane)
(isotretinoin capsules)

Read the Medication Guide that comes with Accutane before you start taking it and each time you get a prescription. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment.

What is the most important information I should know about Accutane?

- Accutane is used to treat a type of severe acne (nodular acne) that has not been helped by other treatments, including antibiotics.
- Because Accutane can cause birth defects, Accutane is only for patients who can understand and agree to carry out all of the instructions in the iPLEDGE program.
- Accutane may cause serious mental health problems.

1. Birth defects (deformed babies), loss of a baby before birth (miscarriage), death of the baby, and early (premature) births. Female patients who are pregnant or who plan to become pregnant must not take Accutane. **Female patients must not get pregnant:**

- for 1 month before starting Accutane
- while taking Accutane
- for 1 month after stopping Accutane.

If you get pregnant while taking Accutane, stop taking it right away and call your doctor. Doctors and patients should report all cases of pregnancy to:

- FDA MedWatch at 1-800-FDA-1088, and
- the iPLEDGE pregnancy registry at 1-866-495-0654

2. Serious mental health problems. Accutane may cause:

- **depression**
- **psychosis** (seeing or hearing things that are not real)
- **suicide.** Some patients taking Accutane have had thoughts about hurting themselves or putting an end to their own lives (suicidal thoughts). Some people tried to end their own lives. And some people have ended their own lives.

41 **Stop Accutane and call your doctor right away if you or a family member**
42 **notices that you have any of the following signs and symptoms of**
43 **depression or psychosis:**

- 44 • start to feel sad or have crying spells
- 45 • lose interest in activities you once enjoyed
- 46 • sleep too much or have trouble sleeping
- 47 • become more irritable, angry, or aggressive than usual (for example,
- 48 temper outbursts, thoughts of violence)
- 49 • have a change in your appetite or body weight
- 50 • have trouble concentrating
- 51 • withdraw from your friends or family
- 52 • feel like you have no energy
- 53 • have feelings of worthlessness or guilt
- 54 • start having thoughts about hurting yourself or taking your own life
- 55 (suicidal thoughts)
- 56 • start acting on dangerous impulses
- 57 • start seeing or hearing things that are not real

58

59 After stopping Accutane, you may also need follow-up mental health care if you
60 had any of these symptoms.

61 **What is Accutane?**

62 Accutane is a medicine taken by mouth to treat the most severe form of acne
63 (nodular acne) that cannot be cleared up by any other acne treatments, including
64 antibiotics. Accutane can cause serious side effects (see **“What is the most**
65 **important information I should know about Accutane?”**). Accutane can only
66 be:

- 67 • prescribed by doctors that are registered in the iPLEDGE program
- 68 • dispensed by a pharmacy that is registered with the iPLEDGE program
- 69 • given to patients who are registered in the iPLEDGE program and agree to do
70 everything required in the program

71 **What is severe nodular acne?**

72 Severe nodular acne is when many red, swollen, tender lumps form in the skin.
73 These can be the size of pencil erasers or larger. If untreated, nodular acne can
74 lead to permanent scars.

75 **Who should not take Accutane?**

- 76 • **Do not take Accutane if you are pregnant, plan to become pregnant, or**
77 **become pregnant during Accutane treatment.** Accutane causes severe birth
78 defects. See **“What is the most important information I should know**
79 **about Accutane?”**

80

81 • **Do not take Accutane if you are allergic to anything in it.** Accutane
82 contains **parabens** as the preservative. See the end of this Medication Guide
83 for a complete list of ingredients in Accutane.
84

85 **What should I tell my doctor before taking Accutane?**

86 **Tell your doctor if you or a family member has any of the following health**
87 **conditions:**

- 88 • mental problems
- 89 • asthma
- 90 • liver disease
- 91 • diabetes
- 92 • heart disease
- 93 • bone loss (osteoporosis) or weak bones
- 94 • an eating problem called anorexia nervosa (where people eat too little)
- 95 • food or medicine allergies

96
97 **Tell your doctor if you are pregnant or breastfeeding. Accutane must not be**
98 **used by women who are pregnant or breastfeeding.**

99 **Tell your doctor about all of the medicines you take including prescription**
100 **and non-prescription medicines, vitamins and herbal supplements.** Accutane
101 and certain other medicines can interact with each other, sometimes causing
102 serious side effects. Especially tell your doctor if you take:

- 103 • **Vitamin A supplements.** Vitamin A in high doses has many of the same side
104 effects as Accutane. Taking both together may increase your chance of getting
105 side effects.
- 106 • **Tetracycline antibiotics.** Tetracycline antibiotics taken with Accutane can
107 increase the chances of getting increased pressure in the brain.
- 108 • **Progestin-only birth control pills (mini-pills).** They may not work while
109 you take Accutane. Ask your doctor or pharmacist if you are not sure what
110 type you are using.
- 111 • **Dilantin (phenytoin).** This medicine taken with Accutane may weaken your
112 bones.
- 113 • **Corticosteroid medicines.** These medicines taken with Accutane may
114 weaken your bones.
- 115 • **St. John's Wort.** This herbal supplement may make birth control pills work
116 less effectively.

117
118 **These medicines should not be used with Accutane unless your doctor tells**
119 **you it is okay.**

120 Know the medicines you take. Keep a list of them to show to your doctor and
121 pharmacist. Do not take any new medicine without talking with your doctor.

122 **How should I take Accutane?**

- 123 • You must take Accutane exactly as prescribed. You must also follow all the
124 instructions of the iPLEDGE program. Before prescribing Accutane, your
125 doctor will:
- 126 • explain the iPLEDGE program to you
 - 127 • have you sign the Patient Information/Informed Consent (for all patients).
128 Female patients who can get pregnant must also sign another consent
129 form.

130
131 **You will not be prescribed Accutane if you cannot agree to or follow all**
132 **the instructions of the iPLEDGE program.**

- 133 • You will get no more than a 30-day supply of Accutane at a time. This is to
134 make sure you are following the Accutane iPLEDGE program. You should
135 talk with your doctor each month about side effects.
136
- 137 • The amount of Accutane you take has been specially chosen for you. It is
138 based on your body weight, and may change during treatment.
139
- 140 • Take Accutane 2 times a day with a meal, unless your doctor tells you
141 otherwise. **Swallow your Accutane capsules whole with a full glass of**
142 **liquid. Do not chew or suck on the capsule.** Accutane can hurt the tube that
143 connects your mouth to your stomach (esophagus) if it is not swallowed
144 whole.
145
- 146 • If you miss a dose, just skip that dose. Do **not** take 2 doses at the same time.
147
- 148 • If you take too much Accutane or overdose, call your doctor or poison control
149 center right away.
- 150
- 151 • Your acne may get worse when you first start taking Accutane. This should
152 last only a short while. Talk with your doctor if this is a problem for you.
153
- 154 • You must return to your doctor as directed to make sure you don't have signs
155 of serious side effects. Your doctor may do blood tests to check for serious
156 side effects from Accutane. Female patients who can get pregnant will get a
157 pregnancy test each month.
158
- 159 • Female patients who can get pregnant must agree to use 2 separate forms of
160 effective birth control at the same time 1 month before, while taking, and for 1
161 month after taking Accutane. **You must access the iPLEDGE system to**
162 **answer questions about the program requirements and to enter your 2**
163 **chosen forms of birth control.** To access the iPLEDGE system, go to
164 www.ipledgeprogram.com or call 1-866-495-0654.
165

166 You must talk about effective birth control methods with your doctor or go for
167 a free visit to talk about birth control with another doctor or family planning

168 expert. Your doctor can arrange this free visit, which will be paid for by the
169 company that makes Accutane.

170 **If you have sex at any time without using 2 forms of effective birth**
171 **control, get pregnant, or miss your expected period, stop using Accutane**
172 **and call your doctor right away.**

173 **What should I avoid while taking Accutane?**

- 174 • **Do not get pregnant** while taking Accutane and for 1 month after stopping
175 Accutane. See “**What is the most important information I should know**
176 **about Accutane?**”
177
- 178 • **Do not breast feed** while taking Accutane and for 1 month after stopping
179 Accutane. We do not know if Accutane can pass through your milk and harm
180 the baby.
181
- 182 • **Do not give blood** while you take Accutane and for 1 month after stopping
183 Accutane. If someone who is pregnant gets your donated blood, her baby may
184 be exposed to Accutane and may be born with birth defects.
185
- 186 • **Do not take other medicines or herbal products** with Accutane unless you
187 talk to your doctor. See “**What should I tell my doctor before taking**
188 **Accutane?**”
189
- 190 • **Do not drive at night until you know if Accutane has affected your vision.**
191 Accutane may decrease your ability to see in the dark.
192
- 193 • **Do not have cosmetic procedures to smooth your skin, including waxing,**
194 **dermabrasion, or laser procedures, while you are using Accutane and for**
195 **at least 6 months after you stop.** Accutane can increase your chance of
196 scarring from these procedures. Check with your doctor for advice about when
197 you can have cosmetic procedures.
198
- 199 • **Avoid sunlight and ultraviolet lights** as much as possible. Tanning machines
200 use ultraviolet lights. Accutane may make your skin more sensitive to light.
201
- 202 • **Do not share Accutane with other people.** It can cause birth defects and
203 other serious health problems.
204

205 **What are the possible side effects of Accutane?**

- 206 • **Accutane can cause birth defects (deformed babies), loss of a baby before**
207 **birth (miscarriage), death of the baby, and early (premature) births.** See
208 “**What is the most important information I should know about**
209 **Accutane?**”
210
- 211 • **Accutane may cause serious mental health problems.** See “**What is the**
212 **most important information I should know about Accutane?**”

- 213 • **serious brain problems.** Accutane can increase the pressure in your brain.
214 This can lead to permanent loss of eyesight and, in rare cases, death. Stop
215 taking Accutane and call your doctor right away if you get any of these signs
216 of increased brain pressure:
- 217 • bad headache
 - 218 • blurred vision
 - 219 • dizziness
 - 220 • nausea or vomiting
 - 221 • seizures (convulsions)
 - 222 • stroke
 - 223
- 224 • **skin problems.** Skin rash can occur in patients taking Accutane. In some
225 patients a rash can be serious. Stop using Accutane and call your doctor right
226 away if you develop conjunctivitis (red or inflamed eyes, like “pink eye”), a
227 rash with a fever, blisters on legs, arms or face and/or sores in your mouth,
228 throat, nose, eyes, or if your skin begins to peel.
- 229 • **stomach area (abdomen) problems.** Certain symptoms may mean that your
230 internal organs are being damaged. These organs include the liver, pancreas,
231 bowel (intestines), and esophagus (connection between mouth and stomach).
232 If your organs are damaged, they may not get better even after you stop taking
233 Accutane. Stop taking Accutane and call your doctor if you get:
- 234 • severe stomach, chest or bowel pain
 - 235 • trouble swallowing or painful swallowing
 - 236 • new or worsening heartburn
 - 237 • diarrhea
 - 238 • rectal bleeding
 - 239 • yellowing of your skin or eyes
 - 240 • dark urine
 - 241
- 242 • **bone and muscle problems.** Accutane may affect bones, muscles, and
243 ligaments and cause pain in your joints or muscles. Tell your doctor if you
244 plan hard physical activity during treatment with Accutane. Tell your doctor if
245 you get:
- 246 • back pain
 - 247 • joint pain
 - 248 • broken bone. Tell all healthcare providers that you take Accutane if you
249 break a bone.
 - 250
- 251 **Stop Accutane and call your doctor right away if you have muscle**
252 **weakness. Muscle weakness with or without pain can be a sign of**
253 **serious muscle damage.**
- 254 Accutane may stop long bone growth in teenagers who are still growing.

255 • **hearing problems.** Stop using Accutane and call your doctor if your hearing
256 gets worse or if you have ringing in your ears. Your hearing loss may be
257 permanent.

258 • **vision problems.** Accutane may affect your ability to see in the dark. This
259 condition usually clears up after you stop taking Accutane, but it may be
260 permanent. Other serious eye effects can occur. Stop taking Accutane and call
261 your doctor right away if you have any problems with your vision or dryness
262 of the eyes that is painful or constant. If you wear contact lenses, you may
263 have trouble wearing them while taking Accutane and after treatment.

264 • **lipid (fats and cholesterol in blood) problems.** Accutane can raise the level
265 of fats and cholesterol in your blood. This can be a serious problem. Return to
266 your doctor for blood tests to check your lipids and to get any needed
267 treatment. These problems usually go away when Accutane treatment is
268 finished.

269 • **serious allergic reactions.** Stop taking Accutane and get emergency care
270 right away if you develop hives, a swollen face or mouth, or have trouble
271 breathing. Stop taking Accutane and call your doctor if you get a fever, rash,
272 or red patches or bruises on your legs.

273 • **blood sugar problems.** Accutane may cause blood sugar problems including
274 diabetes. Tell your doctor if you are very thirsty or urinate a lot.

275 • **decreased red and white blood cells.** Call your doctor if you have trouble
276 breathing, faint, or feel weak.

277 • **The common, less serious side effects of Accutane** are dry skin, chapped
278 lips, dry eyes, and dry nose that may lead to nosebleeds. Call your doctor if
279 you get any side effect that bothers you or that does not go away.

280 These are not all of the possible side effects with Accutane. Your doctor or
281 pharmacist can give you more detailed information. Call your doctor for medical
282 advice about side effects. You may report side effects to FDA at 1-800-FDA-1088
283 or Roche at 1-800-526-6367.

284 **How should I store Accutane?**

285 • Store Accutane at room temperature, between 59° and 86°F. Protect from
286 light.

287 • **Keep Accutane and all medicines out of the reach of children.**

288 **General Information about Accutane**

289 Medicines are sometimes prescribed for conditions that are not mentioned in
290 Medication Guides. Do not use Accutane for a condition for which it was not
291 prescribed. Do not give Accutane to other people, even if they have the same
292 symptoms that you have. It may harm them.
293

294 This Medication Guide summarizes the most important information about
295 Accutane. If you would like more information, talk with your doctor. You can ask
296 your doctor or pharmacist for information about Accutane that is written for
297 health care professionals. You can also call iPLEDGE program at 1-866-495-
298 0654 or visit www.ipledgeprogram.com.

299 **What are the ingredients in Accutane?**

300 **Active Ingredient: Isotretinoin**

301 **Inactive Ingredients:** beeswax, butylated hydroxyanisole, edetate disodium,
302 hydrogenated soybean oil flakes, hydrogenated vegetable oil, and soybean oil.
303 Gelatin capsules contain glycerin and parabens (methyl and propyl), with the
304 following dye systems: 10 mg — iron oxide (red) and titanium dioxide; 20 mg —
305 FD&C Red No. 3, FD&C Blue No. 1, and titanium dioxide; 40 mg — FD&C
306 Yellow No. 6, D&C Yellow No. 10, and titanium dioxide.


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308 This Medication Guide has been approved by the U.S. Food and Drug
309 Administration.

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