

MEDICATION GUIDE**PegIntron™ Redipen® Single-dose Delivery System****Peginterferon alfa-2b****Including appendix with instructions for using PegIntron™ Redipen® Single-dose Delivery System**

Read this Medication Guide carefully before you start taking PegIntron™ (**Peg In-tron**) or PegIntron™/REBETOL (**REB-eh-tole**) combination therapy. Read the Medication Guide each time you refill your prescription because there may be new information. The information in this Medication Guide does not take the place of talking with your health care provider (doctor, nurse, nurse practitioner, or physician's assistant).

If you are taking PegIntron™/REBETOL combination therapy, also read the Medication Guide for REBETOL (ribavirin, USP) Capsules.

What is the most important information I should know about PegIntron™ and PegIntron™/REBETOL combination therapy?

PegIntron™ (peginterferon) is a treatment for some people who are infected with hepatitis C virus. However, PegIntron™ and PegIntron™/REBETOL combination therapy can have serious side effects that may cause death in rare cases. Before you decide to start treatment, you should talk to your health care provider about the possible benefits and side effects of PegIntron™ or PegIntron™/REBETOL combination therapy. If you begin treatment you will need to see your health care provider regularly for medical examinations and lab tests to make sure your treatment is working and to check for side effects.

REBETOL capsules may cause birth defects and/or death of an unborn child. If you are pregnant, you or your male partner must not take PegIntron™/REBETOL combination therapy. You must not become pregnant while either you or your partner are being treated with the combination PegIntron™/REBETOL therapy, or for 6 months after stopping therapy. Men and women should use birth control while taking the combination therapy and for 6 months afterwards. If you or your partner are being treated and you become pregnant, either during treatment or within 6 months of stopping treatment, call your health care provider right away. There is a Ribavirin Pregnancy Registry that collects information about pregnancy outcomes in female patients and female partners of male patients exposed to ribavirin. You or your health care provider are encouraged to contact the Registry at 1-800-593-2214.

If you are taking PegIntron™ or PegIntron™/REBETOL therapy you should call your health care provider immediately if you develop any of these symptoms:

New or worsening mental health problems, such as thoughts about killing or hurting yourself or others, trouble breathing, chest pain, severe stomach or lower back pain,



46 **bloody diarrhea or bloody bowel movements, high fever, bruising, bleeding, or**
47 **decreased vision.**

48

49 The most serious possible side effects of PegIntron™ and PegIntron™/REBETOL therapy
50 include:

51

52 **Problems with Pregnancy.** Combination PegIntron™/REBETOL therapy can cause
53 **death, serious birth defects, or other harm to your unborn child. If you are a woman of**
54 **childbearing age, you must not become pregnant during treatment and for 6 months**
55 **after you have stopped therapy. You must have a negative pregnancy test immediately**
56 **before beginning treatment, during treatment, and for 6 months after you have stopped**
57 **therapy.** Both males and female patients must use effective forms of birth control
58 **during treatment and for the 6 months after treatment is completed. Male patients**
59 **should use a condom.** If you are a female, you must use birth control even if you believe
60 that you are not fertile or that your fertility is low. You should talk to your health care
61 provider about birth control for you and your partner.

62

63 **Mental health problems and suicide.** PegIntron™ and PegIntron™/REBETOL therapies
64 may cause patients to develop mood or behavioral problems. These can include irritability
65 (getting easily upset) and depression (feeling low, feeling bad about yourself, or feeling
66 hopeless). Some patients may have aggressive behavior. Former drug addicts may fall back
67 into drug addiction or overdose. Some patients think about hurting or killing themselves or
68 other people and some have killed (suicide) or hurt themselves or others. You must tell your
69 health care provider if you are being treated for a mental illness or had treatment in the past
70 for any mental illness, including depression and suicidal behavior. You should tell your
71 health care provider if you have ever been addicted to drugs or alcohol.

72

73 **Heart problems.** Some patients taking PegIntron™ or PegIntron™/REBETOL therapy
74 may develop problems with their heart, including low blood pressure, fast heart rate, and
75 very rarely, heart attacks. Tell your health care provider if you have had any heart problems
76 in the past.

77

78 **Blood problems.** PegIntron™ and PegIntron™/REBETOL therapies commonly lower two
79 types of blood cells (white blood cells and platelets). In some patients, these blood counts
80 may fall to dangerously low levels. If your blood counts become very low, this could lead to
81 infections or bleeding.

82

83 REBETOL therapy causes a decrease in the number of red blood cells you have (anemia).
84 This can be dangerous, especially for patients who already have heart or circulatory
85 (cardiovascular) problems. Talk with your health care provider before taking combination
86 PegIntron™/REBETOL therapy if you have, or have ever had any cardiovascular problems.

87

88 **Body organ problems.** Certain symptoms like severe stomach pain may mean that your
89 internal organs are being damaged.

90



91 *For other possible side effects, see “What are the possible side effects of PegIntron™ and*
92 *PegIntron™/REBETOL” in this Medication Guide.*

93

94 **What is PegIntron™ and PegIntron™/REBETOL combination therapy?**

95 The PegIntron™ product is a drug used to treat adults who have a lasting (chronic) infection
96 with hepatitis C virus and who show signs that the virus is damaging the liver.

97

98 PegIntron™/REBETOL combination therapy consists of two medications also used to treat
99 hepatitis C infection. Patients with hepatitis C have the virus in their blood and in their liver.
100 PegIntron™ reduces the amount of virus in the body and helps the body's immune system
101 fight the virus. REBETOL (ribavirin) is a drug that helps to fight the viral infection, but does
102 not work when used by itself to treat chronic hepatitis C.

103

104 It is not known if PegIntron™ or PegIntron™/REBETOL therapies can cure hepatitis C
105 (permanently eliminate the virus), or if it can prevent liver failure or liver cancer that is
106 caused by hepatitis C infection.

107

108 It is also not known if PegIntron™ or PegIntron™/REBETOL combination therapy will
109 prevent one infected person from infecting another person with hepatitis C.

110

111 **Who should not take PegIntron™ or PegIntron™/REBETOL therapy?**

112 Do not take PegIntron™ or PegIntron™/REBETOL therapy if you:

113 • are pregnant, planning to get pregnant during treatment or during the 6 months after
114 treatment, or breast-feeding

115

116 • are a male patient with a female sexual partner who is pregnant, or plans to become
117 pregnant at any time while you are being treated with REBETOL, or during the 6
118 months after your treatment has ended.

119

120 • have hepatitis caused by your immune system attacking your liver (autoimmune
121 hepatitis) or unstable liver disease

122

123 • had an allergic reaction to another alpha interferon or are allergic to any of the
124 ingredients in PegIntron™ or REBETOL Capsules. If you have any doubts, ask your
125 health care provider.

126

127 • Do not take PegIntron™/REBETOL combination therapy if you have abnormal red
128 blood cells such as sickle-cell anemia or thalassemia major.

129

130 **If you have any of the following conditions or serious medical problems, discuss them**
131 **with your health care provider before taking PegIntron™ or PegIntron™/REBETOL**
132 **therapy:**

133 • depression or anxiety

134 • sleep problems

135 • high blood pressure

136 • previous heart attack, or other heart problems



- 137 • liver problems (other than hepatitis C infection)
- 138 • any kind of autoimmune disease (where the body's immune system attacks the body's
- 139 own cells), such as psoriasis, systemic lupus erythematosus, rheumatoid arthritis
- 140 • thyroid problems
- 141 • diabetes
- 142 • colitis (inflammation of the bowels)
- 143 • cancer
- 144 • hepatitis B infection
- 145 • HIV infection
- 146 • kidney problems
- 147 • bleeding problems
- 148 • alcoholism
- 149 • drug abuse or addiction
- 150 • body organ transplant and are taking medicine that keeps your body from rejecting your
- 151 transplant (suppresses your immune system).

152

153 **How should I take PegIntron™ or PegIntron™/REBETOL?**

154 Your health care provider will decide whether you will take PegIntron™ therapy alone or the
155 combination of PegIntron™/REBETOL, as well as the correct dose (based on your weight).
156 PegIntron™ and PegIntron™/REBETOL are given for one year. Take your prescribed dose
157 of PegIntron™ **ONCE A WEEK**, on the same day of each week and at approximately the
158 same time. Take the medicine for the full year and do not take more than the prescribed
159 dose. REBETOL Capsules should be taken with food. When you take REBETOL with
160 food, more of the medicine (70% more on average) is taken up by your body. You should
161 take REBETOL the same way every day (twice a day with food) to keep the medicine in
162 your body at a steady level. This will help your health care provider to decide how your
163 treatment is working and how to change the number of REBETOL capsules you take if you
164 have side effects from REBETOL. **Be sure to read the Medication Guide for REBETOL**
165 **(ribavirin, USP) for complete instructions on how to take the REBETOL capsules.**

166

167 You should be completely comfortable with how to prepare PegIntron™; how to set the dose
168 you take; and how to inject yourself before you use PegIntron™ for the first time.
169 PegIntron™ comes in two different forms, a powder in a single-use vial and a Redipen®
170 single-use delivery system. See the attached appendix for detailed instructions for preparing
171 and giving a dose of PegIntron™.

172

173 If you miss a dose of the PegIntron™ product, take the missed dose as soon as possible
174 during the same day or the next day, then continue on your regular dosing schedule. If
175 several days go by after you miss a dose, check with your health care provider about what to
176 do. Do not double the next dose or take more than one dose a week without talking to your
177 health care provider. Call your health care provider right away if you take more than your
178 prescribed PegIntron™ dose. Your health care provider may wish to examine you more
179 closely, and take blood for testing.

180



181 If you miss a dose of REBETOL capsules, take the missed dose as soon as possible during
182 the same day. If an entire day has gone by, check with your health care provider about what
183 to do. Do not double the next dose.

184

185 You must get regular blood tests to help your health care provider check how the treatment
186 is working and to check for side effects.

187

188 Tell your health care provider if you are taking or planning to take other prescription or non-
189 prescription medicines, including vitamin and mineral supplements and herbal medicines.

190

191 **What should I avoid while taking PegIntron™ or PegIntron™/REBETOL therapies?**

192 • If you are pregnant do not start taking PegIntron™/REBETOL combination therapy.

193 • Avoid becoming pregnant while taking PegIntron™ or PegIntron™/REBETOL.

194 PegIntron™ and PegIntron™/REBETOL may harm your unborn child (death or serious birth
195 defects) or cause you to lose your baby (miscarry). **If you or your partner becomes**
196 **pregnant during treatment or during the 6 months after treatment with**
197 **PegIntron™/REBETOL combination therapy, immediately report the pregnancy to**
198 **your health care provider. You or your health care provider should call 1-800-593-**
199 **2214.** By calling this number, information about you and/or your partner will be added to a
200 pregnancy registry that will be used to help you and your health care provider make decisions
201 about your treatment for hepatitis in the future. You, your partner, and/or your health care
202 provider will be asked to provide follow-up information on the outcome of the pregnancy.

203

204 • Do not breast-feed your baby while taking PegIntron™.

205

206 **What are the possible side effects of PegIntron™ and PegIntron™/REBETOL**
207 **combination therapy?**

208

209 **Possible, serious side effects include:**

210 **Mental health problems including suicide, blood problems, heart problems, body organ**
211 **problems.** See “What is the most important information I should know about PegIntron™
212 and PegIntron™/REBETOL combination therapy?”

213

214 **Other body organ problems.** A few patients have lung problems (such as pneumonia or
215 inflammation of the lung tissue), inflammation of the kidney, and eye disorders.

216

217 **New or worsening autoimmune disease.** Some patients taking PegIntron™ or
218 PegIntron™/REBETOL develop autoimmune diseases (a condition where the body’s
219 immune cells attack other cells or organs in the body), including rheumatoid arthritis,
220 systemic lupus erythematosus, and psoriasis. In some patients who already have an
221 autoimmune disease, the disease worsens on PegIntron™ and PegIntron™/REBETOL
222 combination therapy.

223

224 **Common but less serious side effects include:**

225



226 **Flu-like symptoms.** Most patients who take PegIntron™ or PegIntron™/REBETOL therapy
227 have "flu-like" symptoms (headache, muscle aches, tiredness, and fever). Some of these
228 symptoms (fever, headache) usually lessen after the first few weeks of therapy. You can
229 reduce some of these symptoms by injecting your PegIntron™ dose at bedtime. Over-the-
230 counter pain and fever reducers, such as acetaminophen or ibuprofen, can be used to prevent
231 or reduce the fever and headache.

232

233 **Extreme fatigue (tiredness).** Many patients become extremely tired while on PegIntron™
234 or PegIntron™/REBETOL combination therapy.

235

236 **Appetite problems.** Nausea, loss of appetite, and weight loss, occur commonly.

237

238 **Thyroid problems.** Some patients develop changes in the function of their thyroid.
239 Symptoms of thyroid changes include the inability to concentrate, feeling cold or hot all the
240 time, a change in your weight, and changes to your skin.

241 **Blood sugar problems.** Some patients develop problems with the way their body controls
242 their blood sugar and may develop high blood sugar or diabetes.

243

244 **Skin reactions.** Redness, swelling, and itching are common at the site of injection. If after
245 several days these symptoms do not disappear contact your health care provider. You may
246 get a rash during therapy. If this occurs, your health care provider may recommend medicine
247 to treat the rash.

248

249 **Hair thinning.** Hair thinning is common during PegIntron™ and PegIntron™/REBETOL
250 treatment. Hair loss stops and hair growth returns after therapy is stopped.

251

252 These are not all of the side effects of PegIntron™ or PegIntron™/REBETOL combination
253 therapy. Your health care provider or pharmacist can give you a more complete list.

254

255 **General advice about prescription medicines:**

256 Medicines are sometimes prescribed for purposes other than those listed in a Medication
257 Guide. If you have any concerns about PegIntron™, ask your health care provider. Your
258 health care provider or pharmacist can give you information about PegIntron™ that was
259 written for health care professionals. Do not use PegIntron™ for a condition for which it was
260 not prescribed. Do not share this medication with other people.

261

262 **If you are taking PegIntron™/REBETOL combination therapy, also read the**
263 **Medication Guide for REBETOL (ribavirin, USP) Capsules.**

264

265 *This Medication Guide has been approved by the U.S. Food and Drug Administration.*

266

267 **How do I prepare and inject the PegIntron™ Redipen® Dose?**

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269 The PegIntron™ Redipen® system is for a single use, by one person only. The Redipen®
270 must not be shared. Use only the injection needle provided in the packaging for the

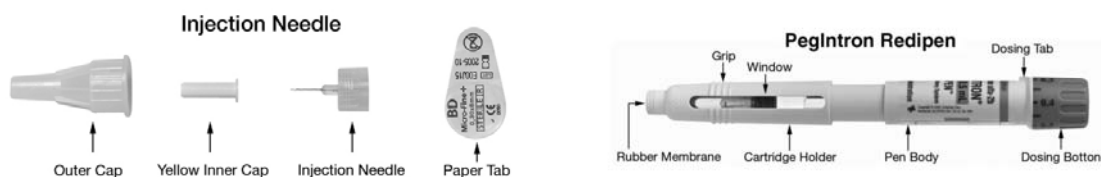


271 PegIntron™ Redipen® system. If you have problems with the Redipen® system or the
 272 PegIntron™ solution, you should contact your health care provider or pharmacist.

273

274 The following instructions explain how to prepare and inject yourself with the PegIntron™
 275 Redipen® system. Please read the instructions carefully and follow them step by step. Your
 276 health care provider will instruct you on how to self-inject with the PegIntron™ Redipen®.
 277 Do not attempt to inject yourself unless you are sure you understand the procedure and
 278 requirements for self-injection.

279



280

281

282 **How to use the PegIntron™ Redipen® single-dose delivery system.**

283

284 **Storing PegIntron™**

285 PegIntron™ Redipen® should be stored in the refrigerator at 2°C to 8°C (36°F to 46°F);
 286 avoid exposure to heat. After mixing, the PegIntron™ solution should be used immediately
 287 but may be stored in the refrigerator up to 24 hours at 2°C to 8°C (36°F to 46°F). The
 288 solution contains no preservatives. DO NOT FREEZE.

289

290 **Preparation**

291

292 1. Find a clean, well-lit, non-slip flat working surface and assemble all of the supplies you
 293 will need for an injection. All of the supplies you will need are in the PegIntron™
 294 Redipen® package. The package contains:

295 ■ a PegIntron™ Redipen® single-dose delivery system

296 ■ one disposable needle

297 ■ two alcohol swabs, and

298 ■ dosing tray; (The dosing tray is the bottom half of the Redipen® package.)

299

300 2. Take the PegIntron™ Redipen® out of the refrigerator and allow the medicine to come to
 301 room temperature. Before removing the Redipen® from the carton, check the expiration
 302 date printed on the PegIntron™ Redipen® carton to make sure that the expiration date
 303 has not passed. Do not use if the expiration date has passed.

304 3. After taking the PegIntron™ Redipen® out of the carton, look in the window of the
 305 Redipen® and make sure the PegIntron™ in the cartridge holder window is a white, to
 306 off-white tablet that is whole, or in pieces, or powdered.

307 4. Wash your hands thoroughly with soap and water, rinse, and towel dry. It is important to
 308 keep your work area, your hands, and the injection site clean to minimize the risk of
 309 infection.

310

311 **1. Mix the Drug**



312

313 **Key points:**

314

315 **Before you mix the PegIntron™, make sure it is at room temperature. It is important**
316 **that you keep the PegIntron™ Redipen® UPRIGHT (Dosing Button down) as shown in**
317 **Figure 1.**

318

319 a. Hold the PegIntron™ Redipen® **UPRIGHT (Figure 1a)** in the dosing tray on a hard,
320 flat, non-slip surface with the dosing button **down**. You may want to hold the Redipen®
321 using the grip.

322

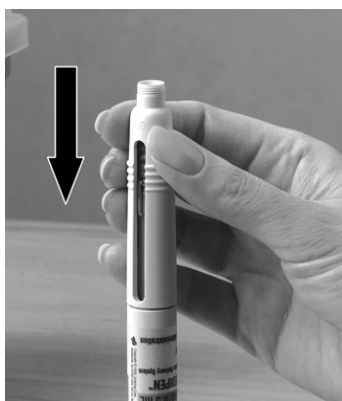
323 b. To mix the powder and the liquid, keep the Redipen® upright in the dosing tray and
324 press the top half of the Redipen® downward toward the hard, flat, non-slip surface **until**
325 **you hear the click** (Figure 1b). Once you've heard the click, you will notice in the
326 window that both dark stoppers are now touching. The dosing button should be flush with
327 the pen body.



328

329 **Figure 1a**

330



331

332 **Figure 1b**

333

334 c. Wait several seconds for the powder to completely dissolve.

335

336 **d. Gently turn the PegIntron™ Redipen® upside down twice (Figure 2). To avoid**
337 **excessive foaming, DO NOT SHAKE.**





338

339 **Figure 2**

340

341 e. Keeping the PegIntron™ Redipen® **UPRIGHT**, with the dosing button down, check
342 through the Redipen® window to see if the mixed PegIntron™ solution is completely
343 dissolved. The solution should be clear, colorless, and without particles **before use**. It is
344 normal to see some small bubbles near the top of the solution. Do not use if the solution
345 is not clear, or if you see particles.

346

347 f. **Place the PegIntron™ Redipen® back into the dosing tray provided in the**
348 **packaging (Figure 3). The dosing button will be on the bottom.**

349

**Figure 3**

350

351

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357 **2. Attach the Needle**

358

- 359 a. Wipe the rubber membrane of the PegIntron™ Redipen® with one alcohol swab.
360 b. Remove the protective paper tab from the injection needle, but do NOT remove either the
361 outer cap or the yellow inner cap from the injection needle. Keeping the PegIntron™ Redipen®
362 **UPRIGHT** in the dosing tray, **FIRMLY** push the injection needle straight into the Redipen®
363 rubber membrane, and screw it firmly in place, in a clockwise direction (**Figure 4**). Remember



364 to leave the needle caps in place when you attach the needle to the Redipen[®]. Pushing the needle
365 through the rubber membrane, “primes” the needle and allows the extra liquid and air in the pen
366 to be removed.
367



Figure 4

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NOTE: Some fluid will trickle out. This is **normal**. The dark stoppers move up and you will no longer see the fluid in the window once the needle is successfully primed.

c. **IMPORTANT:** Keep the Redipen[®] in the UPRIGHT position and keep the outer needle cap on until you are ready to inject.

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3. Dialing the Dose

a. **Remove the PegIntron[™] Redipen[®] from the dosing tray (Figure 5a).**

Holding the PegIntron[™] Redipen[®] firmly, pull the dosing button out as far as it will go. You will see a dark band-

Do not push the dosing button in until you are ready to self-inject the PegIntron[™] dose.

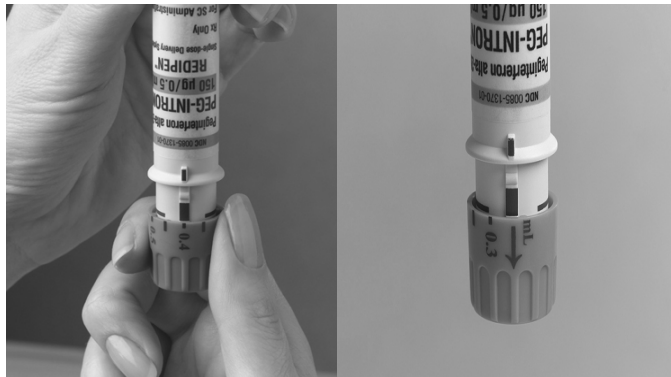




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Figure 5a

b. Turn the dosing button until your prescribed dose is lined up with the dosing tab (**Figure 5b**). The dosing button will turn freely. If you have trouble dialing your dose, check to make sure the dosing button has been pulled out as far as it will go (**Figure 5c**).



394
395

Figure 5b

Figure 5c

396
397
398

c. Carefully lay the PegIntron™ Redipen® down on a hard, flat, non-slip surface. Do NOT remove either of the needle caps and do NOT push the dosing button in until you are ready to self-inject the PegIntron™ dose.

402

4. Injecting the PegIntron™ Dose

404

Choosing an Injection Site

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The best sites for giving yourself an injection are those areas with a layer of fat between the skin and muscle, like your thigh, the outer surface of your upper arm, and abdomen. Do not inject yourself in the area near your navel or waistline. If you are very thin, you should only use the thigh or outer surface of the arm for injection.

410 You should use a different site each time you inject PegIntron™ to avoid soreness at any
411 one site. Do not inject PegIntron™ into an area where the skin is irritated, red, bruised,
412 infected, or has scars, stretch marks, or lumps.

413

414 a. Clean the skin where the injection is to be given with the second alcohol swab provided,
415 and wait for the area to dry.

416 b. Remove the **outer** cap from the needle (**Figure 6a**). There may be some liquid around the
417 yellow inner needle cap (**Figure 6b**). This is normal.

418

419

420



421

422 **Figure 6a**

Figure 6b

423

424 c. Once the injection site is dry, remove the **yellow** inner needle cap (**Figure 6c**). You are
425 now ready to inject.

426



427

428 **Figure 6c**

429

430 **d. Hold the PegIntron™ Redipen® with your fingers wrapped around the pen body**
431 **barrel and your thumb on the dosing button (Figure 7).**

432

433

434

- With your other hand, pinch the skin in the area you have cleaned for injection.
- Insert the needle into the pinched skin at an angle of 45° to 90°.
- Press the dosing button down slowly and firmly until you can't push it any further.



- 435
- 436
- 437
- Keep your thumb pressed down on the dosing button for an additional 5 seconds to ensure that you get the complete dose.
 - Remove the needle from your skin.



438

439 **Figure 7**

440

441 **e. Gently press the injection site with a small bandage or sterile gauze if necessary for a**
442 **few seconds but** do not massage the injection site. If there is bleeding, cover with an
443 adhesive bandage. **DO NOT RECAP THE NEEDLE and DO NOT REUSE the**
444 **Redipen[®].**

445

446 **How do I Dispose of the Redipen[®]?**

447 Discard the Redipen[®] and needle and any solution remaining in the Redipen[®] in a sharps
448 container or other puncture-resistant container like a metal coffee can. DO NOT use glass or
449 clear plastic containers. Ask your health care provider how to dispose of a full container.
450 Always keep the container out of reach of children.

451

452 **After 2 hours, check the injection site for redness, swelling, or tenderness.**
453 **If you have a skin reaction and it doesn't clear up in a few days, contact**
454 **your health care provider.**

455

456

457 Manufactured by: Schering Corporation, Kenilworth, NJ 07033 USA

458 DATE 12/06

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