

1 060308.final draft Med Guide

2
3 **MEDICATION GUIDE**

4 **PegIntron™/REBETOL® Combo Pack containing**
5 **PegIntron™ REDIPEN® Single-dose Delivery System (peginterferon alfa-2b) and**
6 **REBETOL® (ribavirin, USP) Capsules**

7
8 **Including appendix with instructions for using PegIntron™ REDIPEN® Single-dose**
9 **Delivery System**

10
11 Read this Medication Guide carefully before you start taking PegIntron™/REBETOL®
12 Combo Pack containing PegIntron™ (Peg In-tron) and REBETOL® (REB-eh-tole). Read
13 the Medication Guide each time you refill your prescription because there may be new
14 information. The information in this Medication Guide does not take the place of talking with
15 your health care provider (doctor, nurse, nurse practitioner, or physician's assistant).

16
17 **What is the most important information I should know about PegIntron™/REBETOL®**
18 **Combo Pack therapy?**

19
20 PegIntron™/REBETOL® Combo Pack is a treatment for some people who are infected with
21 hepatitis C virus. However, PegIntron™/REBETOL® Combo Pack therapy can have serious
22 side effects that may cause death in rare cases. Before you decide to start treatment, you
23 should talk to your health care provider about the possible benefits and side effects of
24 PegIntron™/REBETOL® Combo Pack therapy. If you begin treatment you will need to see
25 your health care provider regularly for medical examinations and lab tests to make sure your
26 treatment is working and to check for side effects.

27
28 **REBETOL® capsules may cause birth defects and/or death of an unborn child. If you**
29 **are pregnant, you or your male partner must not take PegIntron™/REBETOL® Combo**
30 **Pack therapy. You must not become pregnant while either you or your partner are**
31 **being treated with PegIntron™/REBETOL® Combo Pack therapy, or for 6 months**
32 **after stopping therapy. During this time you must use two forms of birth control and**
33 **you must have pregnancy test to show that you are not pregnant. Men and women**
34 **should use birth control while taking the combination therapy and for 6 months**
35 **afterwards. If you or your partner are being treated and you become pregnant, either**
36 **during treatment or within 6 months of stopping treatment, call your health care**
37 **provider right away. There is a Ribavirin Pregnancy Registry that collects information**
38 **about pregnancy outcomes in female patients and female partners of male patients**
39 **exposed to ribavirin. You or your health care provider are encouraged to contact the**
40 **Registry at 1-800-593-2214.**

41
42 Be assured that any information you tell the Registry will be kept confidential. (See
43 "What should I avoid while taking PegIntron™/REBETOL® Combo Pack therapy?")

44
45 **If you are taking PegIntron™/REBETOL® Combo Pack therapy you should call your**
46 **health care provider immediately if you develop any of these symptoms:**



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47
48 **New or worsening mental health problems, such as thoughts about killing or hurting**
49 **yourself or others, trouble breathing, chest pain, severe stomach or lower back pain,**
50 **bloody diarrhea or bloody bowel movements, high fever, bruising, bleeding, or**
51 **decreased vision.**

52
53 The most serious possible side effects of PegIntron™/REBETOL® Combo Pack therapy
54 include:

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

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

76
77 **Heart problems.** Some patients taking PegIntron™/REBETOL® Combo Pack therapy may
78 develop problems with their heart, including low blood pressure, fast heart rate, and very
79 rarely, heart attacks. Tell your health care provider if you have had any heart problems in the
80 past.

81
82 **Blood problems.** PegIntron™/REBETOL® Combo Pack therapy commonly lowers two
83 types of blood cells (white blood cells and platelets). In some patients, these blood counts
84 may fall to dangerously low levels. If your blood counts become very low, this could lead to
85 infections or bleeding.

86
87 REBETOL® can cause anemia, which is a decrease in the number of red blood cells. This
88 can be dangerous, especially for patients who already have heart or circulatory
89 (cardiovascular) or breathing problems. Talk with your health care provider before taking
90 PegIntron™/REBETOL® Combo Pack therapy if you have, or have ever had any
91 cardiovascular problems. Your health care provider should check your red blood cell count



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92 before you start therapy and often during the first 4 weeks of therapy. Your red blood cell
93 count may be checked more often if you have any heart or breathing problems.

- 94
- 95 • **Do not take REBETOL Capsules or Oral Solution alone to treat hepatitis C**
96 **infection.** REBETOL Capsules should be used in combination with interferon alfa-2b
97 (INTRON A) or in combination with peginterferon alfa-2b (PegIntron) for treating
98 chronic hepatitis C infection in adults. In children, safety and effectiveness of
99 REBETOL Capsules or Oral Solution has only been shown when used in combination
100 with interferon alfa-2b (INTRON A). Your health care provider or pharmacist should
101 give you a copy of the INTRON A or PegIntron Medication Guide. They have
102 additional important information about combination therapy not covered in this guide.
103 PegIntron™/REBETOL® Combo Pack is not approved for the treatment of chronic
104 hepatitis C in children.

105

106 **Body organ problems.** Certain symptoms like severe stomach pain may mean that your
107 internal organs are being damaged. Cases of weakness, loss of coordination, and numbness
108 due to stroke have been reported in patients taking combination PegIntron/REBETOL,
109 including patients with few or no reported risk factors for stroke.

110

111 *For other possible side effects, see "What are the possible side effects of*
112 *PegIntron™/REBETOL® Combo Pack therapy" in this Medication Guide.*

113

114 **What is PegIntron™/REBETOL® Combo Pack therapy?**

115 PegIntron™/REBETOL® Combo Pack consists of two medications used to treat hepatitis C
116 infection. Patients with hepatitis C have the virus in their blood and in their liver.
117 PegIntron™ reduces the amount of virus in the body and helps the body's immune system
118 fight the virus. REBETOL® (ribavirin) is a drug that helps to fight the viral infection, but
119 does not work when used by itself to treat chronic hepatitis C.

120

121 It is not known if PegIntron™/REBETOL® Combo Pack therapy can cure hepatitis C
122 (permanently eliminate the virus), or if it can prevent liver failure or liver cancer that is
123 caused by hepatitis C infection.

124

125 It is also not known if PegIntron™/REBETOL® Combo Pack therapy will prevent one
126 infected person from infecting another person with hepatitis C.

127

128 **Who should not take PegIntron™/REBETOL® Combo Pack therapy?**

129 Do not take PegIntron™/REBETOL® Combo Pack therapy if you:

- 130 • are pregnant, planning to get pregnant during treatment or during the 6 months after
131 treatment, or breast-feeding
- 132
- 133 • are a male patient with a female sexual partner who is pregnant, or plans to become
134 pregnant at any time while you are being treated with REBETOL®, or during the 6
135 months after your treatment has ended.



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- 137 • have hepatitis caused by your immune system attacking your liver (autoimmune
138 hepatitis) or unstable liver disease.
139
- 140 • had an allergic reaction to another alpha interferon or are allergic to any of the
141 ingredients in PegIntron™ or REBETOL® Capsules. If you have any doubts, ask
142 your health care provider.
143
- 144 • Do not take PegIntron™/REBETOL® Combo Pack therapy if you have abnormal red
145 blood cells such as sickle-cell anemia or thalassemia major.
146

147 **If you have any of the following conditions or serious medical problems, discuss them**
148 **with your health care provider before taking PegIntron™/REBETOL® Combo Pack**
149 **therapy:**

- 150 • depression or anxiety
151 • sleep problems
152 • high blood pressure
153 • previous heart attack, or other heart problems
154 • liver problems (other than hepatitis C infection)
155 • any kind of autoimmune disease (where the body's immune system attacks the body's
156 own cells), such as psoriasis, systemic lupus erythematosus, rheumatoid arthritis
157 • thyroid problems
158 • diabetes
159 • colitis (inflammation of the bowels)
160 • cancer
161 • hepatitis B infection
162 • HIV infection
163 • kidney problems
164 • bleeding problems
165 • alcoholism
166 • drug abuse or addiction
167 • body organ transplant and are taking medicine that keeps your body from rejecting your
168 transplant (suppresses your immune system).
169
170

171 **How should I take PegIntron™/REBETOL® Combo Pack therapy?**

172 Your health care provider will determine the correct dose (based on your weight).
173 PegIntron™/REBETOL® Combo Pack therapy is given for one year. Take your prescribed
174 dose of PegIntron™ ONCE A WEEK, on the same day of each week and at approximately
175 the same time. Take the medicine for the full year and do not take more than the prescribed
176 dose. REBETOL® Capsules should be taken with food. It is important to follow your
177 dosing schedule and your health care providers instructions on how to take your medicines.
178 Under no circumstances should REBETOL Capsules be opened, crushed or broken. When
179 you take REBETOL® with food, more of the medicine (70% more on average) is taken up by
180 your body. You should take REBETOL® the same way every day (twice a day with food) to



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181 keep the medicine in your body at a steady level. This will help your health care provider to
 182 decide how your treatment is working and how to change the number of REBETOL®
 183 capsules you take if you have side effects from REBETOL®. **Be sure to read the**
 184 **Medication Guide for PegIntron™/REBETOL® for complete instructions on how to**
 185 **take this medicine.**

186
 187 You should be completely comfortable with how to prepare PegIntron™, how to set the dose
 188 you take, and how to inject yourself before you use PegIntron™ for the first time.
 189 PegIntron™ comes as a REDIPEN® single-use delivery system. See the attached appendix
 190 for detailed instructions for preparing and giving a dose of PegIntron™.

191
 192 If you miss a dose of the PegIntron™ product, take the missed dose as soon as possible
 193 during the same day or the next day, then continue on your regular dosing schedule. If
 194 several days go by after you miss a dose, check with your health care provider about what to
 195 do. Do not double the next dose or take more than one dose a week without talking to your
 196 health care provider. Call your health care provider right away if you take more than your
 197 prescribed PegIntron™ dose. Your health care provider may wish to examine you more
 198 closely, and take blood for testing.

199
 200 If you miss a dose of REBETOL® capsules, take the missed dose as soon as possible during
 201 the same day. If an entire day has gone by, check with your health care provider about what
 202 to do. Do not double the next dose.

203
 204 You must get regular blood tests to help your health care provider check how the treatment is
 205 working and to check for side effects.

206
 207 Tell your health care provider if you are taking or planning to take other prescription or non-
 208 prescription medicines, including vitamin and mineral supplements and herbal medicines.

209
 210 **What should I avoid while taking PegIntron™/REBETOL® Combo Pack therapy?**

211 • If you are pregnant do not start taking PegIntron™/REBETOL® Combo Pack therapy.
 212 • Avoid becoming pregnant while taking PegIntron™/REBETOL® Combo Pack therapy.
 213 PegIntron™/REBETOL® Combo Pack therapy may harm your unborn child (death or serious
 214 birth defects) or cause you to lose your baby (miscarry). **If you or your partner becomes**
 215 **pregnant during treatment or during the 6 months after treatment with**
 216 **PegIntron™/REBETOL® Combo Pack therapy, immediately report the pregnancy to**
 217 **your health care provider. You or your health care provider should call 1-800-593-**
 218 **2214.** By calling this number, information about you and/or your partner will be added to a
 219 pregnancy registry that will be used to help you and your health care provider make decisions
 220 about your treatment for hepatitis in the future. You, your partner, and/or your health care
 221 provider will be asked to provide follow-up information on the outcome of the pregnancy. Be
 222 assured that any information you tell the Registry will be kept confidential.

223
 224
 225 • **Breastfeeding.** The medicine may pass through your milk and harm the baby.



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- 226 • **Drinking alcohol**, including beer, wine, and liquor. This may make your liver disease
227 worse.
- 228 • **Taking other medicines.** Take only medicines prescribed or approved by your health
229 care provider. These include prescription and nonprescription medicines and herbal
230 supplements.

231

232 **What are the most common side effects of REBETOL Capsules and Oral Solution?**

233 **The most serious possible side effects of REBETOL Capsules and Oral Solution are:**

234

- 235 • **Harm to unborn children.** REBETOL Capsules and Oral Solution may cause birth
236 defects or death of an unborn child. (For more details, see “**What is the most**
237 **important information I should know about REBETOL Capsules or Oral**
238 **Solution?**”)
- 239
- 240 • **Anemia.** Anemia is a reduction in the number of red blood cells you have which can be
241 dangerous, especially if you have heart or breathing problems. Tell your health care
242 provider right away if you feel tired, have chest pain or shortness of breath. These
243 may be signs of low red blood cell counts.
- 244
- 245 • Do not breast-feed your baby while taking PegIntron™.

246

247 **What are the possible side effects of PegIntron™/REBETOL® Combo Pack therapy?**

248

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

250 **Mental health problems including suicide, blood problems, heart problems, body organ**
251 **problems.** See “What is the most important information I should know about
252 PegIntron™/REBETOL® Combo Pack therapy?”

253

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

256

257 **New or worsening autoimmune disease.** Some patients taking PegIntron™/REBETOL®
258 Combo Pack therapy develop autoimmune diseases (a condition where the body’s immune
259 cells attack other cells or organs in the body), including rheumatoid arthritis, systemic lupus
260 erythematosus, and psoriasis. In some patients who already have an autoimmune disease, the
261 disease worsens on PegIntron™/REBETOL® Combo Pack therapy.

262

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

264

265 **Flu-like symptoms.** Most patients who take PegIntron™/REBETOL® Combo Pack therapy
266 have “flu-like” symptoms (headache, muscle aches, tiredness, and fever). Some of these
267 symptoms (fever, headache) usually lessen after the first few weeks of therapy. You can
268 reduce some of these symptoms by injecting your PegIntron™ dose at bedtime. Over-the-
269 counter pain and fever reducers, such as acetaminophen or ibuprofen, can be used to prevent
270 or reduce the fever and headache.

271



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272 **Extreme fatigue (tiredness).** Many patients become extremely tired while on
273 PegIntron™/REBETOL® Combo Pack therapy.

274

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

276

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

280

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

283

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

288

289 **Hair thinning.** Hair thinning is common during PegIntron™/REBETOL® Combo Pack
290 treatment. Hair loss stops and hair growth returns after therapy is stopped.

291

292 These are not all of the side effects of PegIntron™/REBETOL® Combo Pack therapy. Your
293 health care provider or pharmacist can give you a more complete list.

294

295 Call your doctor for medical advice about side effects. You may report side effects to FDA at
296 1-800-FDA-1088.

297

298 **General advice about prescription medicines:**

299 Medicines are sometimes prescribed for purposes other than those listed in a Medication
300 Guide. If you have any concerns about PegIntron™/REBETOL® Combo Pack therapy, ask
301 your health care provider. Your health care provider or pharmacist can give you information
302 about PegIntron™/REBETOL® Combo Pack therapy that was written for health care
303 professionals. Do not use PegIntron™/REBETOL® Combo Pack therapy for a condition for
304 which it was not prescribed. Do not share this medication with other people.

305

306

307 **How do I store my PegIntron™/REBETOL® Combo Pack package?**

308

309 The PegIntron™/REBETOL® Combo Pack package should be stored in the refrigerator at 2°-
310 8°C (36°-46°F).

311

312 When separated, the individual bottle of REBETOL® Capsules should be stored at room
313 temperature 25°C (77°F).

314

315 When separated, the PegIntron™ REDIPEN® should be stored in the refrigerator at 2°-8°C
316 (36°-46°F); avoid exposure to heat. After mixing, the PegIntron™ solution should be used



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317 immediately but may be stored in the refrigerator up to 24 hours at 2°-8°C (36°-46°F). The
 318 solution contains no preservatives. DO NOT FREEZE.

319

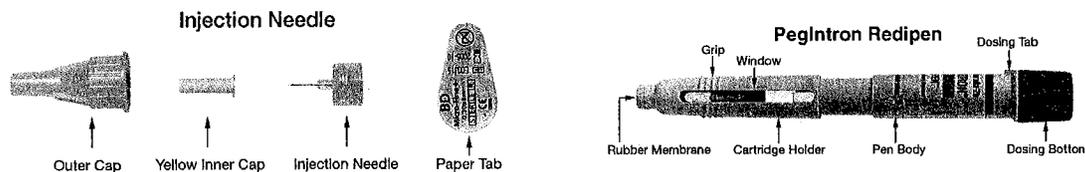
320 How do I prepare and inject the PegIntron™ REDIPEN® Dose?

321

322 The PegIntron™ REDIPEN® system is for a single use, by one person only, ONCE A
 323 WEEK. The REDIPEN® must not be shared. Use only the injection needle provided in the
 324 packaging for the PegIntron™ REDIPEN® system. If you have problems with the
 325 REDIPEN® system or the PegIntron™ solution, you should contact your health care
 326 provider, or pharmacist.

327

328 The following instructions explain how to prepare and inject yourself with the PegIntron™
 329 REDIPEN® system. Please read the instructions carefully and follow them step by step. Your
 330 health care provider will instruct you on how to self-inject with the PegIntron™ REDIPEN®.
 331 Do not attempt to inject yourself unless you are sure you understand the procedure and
 332 requirements for self-injection.



333

334

335 How to use the PegIntron™ REDIPEN® Single-dose Delivery System.

336

337 Preparation

338

- 339 1. Find a clean, well-lit, non-slip flat working surface and assemble all of the supplies you
 340 will need for an injection. All of the supplies you will need are in the PegIntron™
 341 REDIPEN® package. The package contains:
 342 ▪ a PegIntron™ REDIPEN® Single-dose Delivery System
 343 ▪ one disposable needle
 344 ▪ two alcohol swabs, and
 345 ▪ dosing tray (The dosing tray is the bottom half of the REDIPEN® package.)
 346
- 347 2. Take the PegIntron™ REDIPEN® out of the refrigerator and allow the medicine to come
 348 to room temperature. Before removing the REDIPEN® from the carton, check the
 349 expiration date printed on the PegIntron™ REDIPEN® carton to make sure that the
 350 expiration date has not passed. Do not use if the expiration date has passed.
- 351 3. After taking the PegIntron™ REDIPEN® out of the carton, look in the window of the
 352 REDIPEN® and make sure the PegIntron™ in the cartridge holder window is a white, to
 353 off- white tablet that is whole, in pieces, or powdered.
- 354 4. Wash your hands thoroughly with soap and water, rinse, and towel dry. It is important
 355 to keep your work area, your hands, and the injection site clean to minimize the risk of
 356 infection.



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357

358

1. Mix the Drug

359

360

Key points:

361

362

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

363

364

365

366

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

367

368

369

370

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

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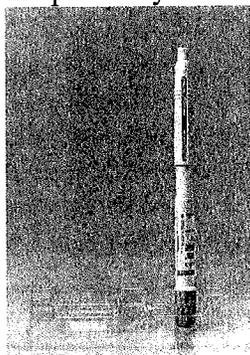


Figure 1a

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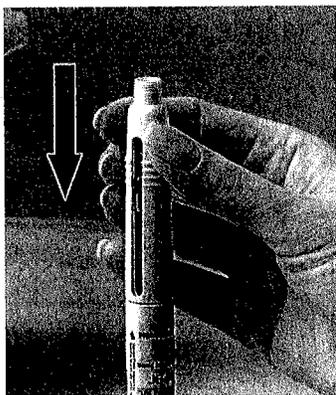


Figure 1b

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381

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

382

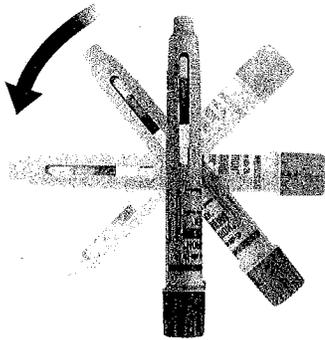
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385

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



386
387

Figure 2

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e. Keep the PegIntron™ REDIPEN® **UPRIGHT**, with the dosing button down. Then, look through the REDIPEN® window to see that the mixed PegIntron™ solution is completely dissolved. The solution should be clear and colorless **before use**. Before attaching the needle, it is normal to see some small bubbles in the REDIPEN® window, near the top of the solution. Do not use the solution if it is discolored, or not clear, or if particulates are present.

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

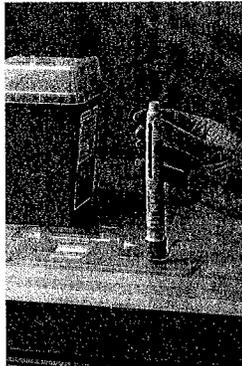


Figure 3

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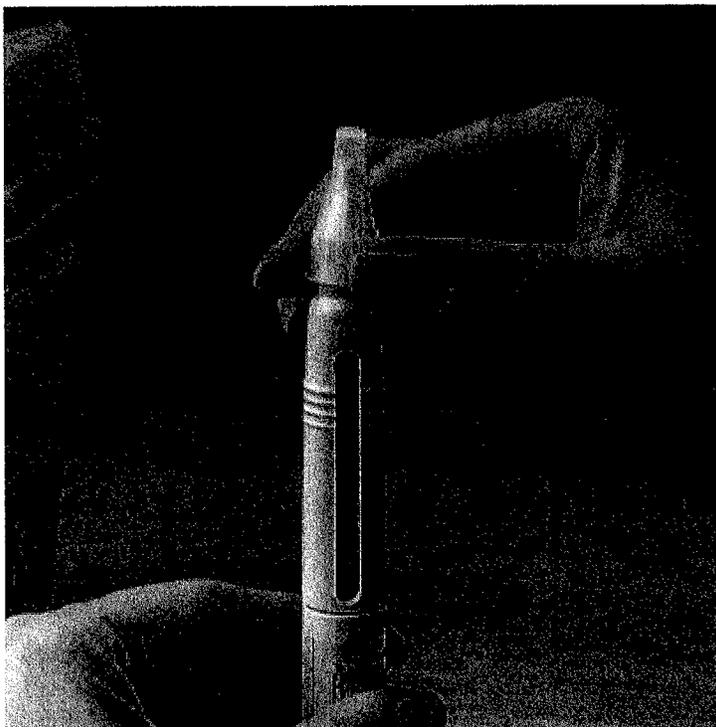
2. Attach the Needle

a. Wipe the rubber membrane of the PegIntron™ REDIPEN® with one alcohol swab.



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409 b. Remove the protective paper tab from the injection needle, but do NOT remove either the
 410 outer cap or the yellow inner cap from the injection needle. Keeping the PegIntron™ REDIPEN®
 411 UPRIGHT in the dosing tray, FIRMLY push the injection needle straight into the REDIPEN®
 412 rubber membrane, and screw it firmly in place, in a clockwise direction (**Figure 4**). Remember
 413 to leave the needle caps in place when you attach the needle to the REDIPEN®. Pushing the
 414 needle through the rubber membrane, “primes” the needle and allows the extra liquid and air in
 415 the pen to be removed.
 416



417
 418 **Figure 4**
 419

420 NOTE: Some fluid will trickle out. This is **normal**. The dark stoppers move up and you will no
 421 longer see the fluid in the window once the needle is successfully primed.
 422

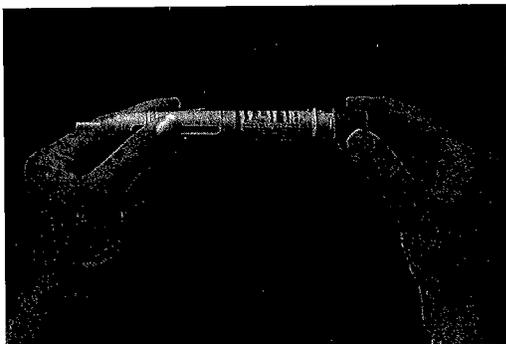
423
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 426 **3. Dialing the Dose**
 427

428 a. **Remove the PegIntron™ REDIPEN® from the dosing tray (Figure 5a).**
 429 Holding the PegIntron™ REDIPEN® firmly, pull the dosing button out as far as it will
 430 go. -You will see a dark band-
 431

432 **Do not push the dosing button in until you are ready to self-inject the PegIntron™**
 433 **dose.**
 434

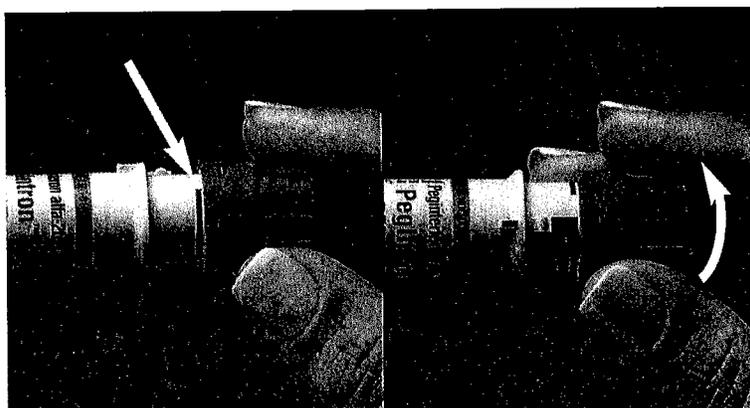


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435
436 **Figure 5a**
437

438 b. Turn the dosing button until your prescribed dose is lined up with the dosing tab (**Figure 5b**).
439 The dosing button will turn freely. If you have trouble dialing your dose, check to make sure the
440 dosing button has been pulled out as far as it will go (**Figure 5c**).
441



442
443
444
445 **Figure 5b**

Figure 5c

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447
448
449 c. Carefully lay the PegIntron™ REDIPEN® down on a hard, flat, non-slip surface. Do NOT
450 remove either of the needle caps and do NOT push the dosing button in until you are ready to
451 self-inject the PegIntron™ dose.
452

453 **4. Injecting the PegIntron™ Dose**

454 **Choosing an Injection Site**

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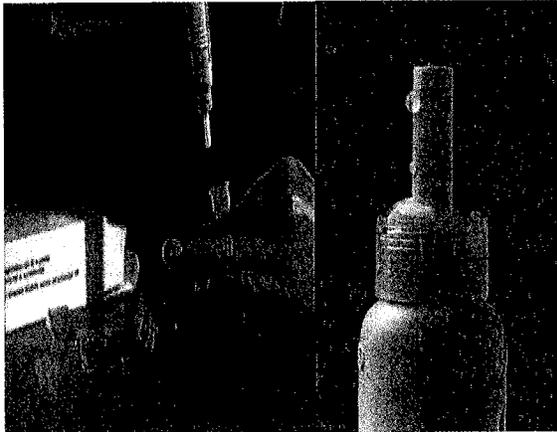


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460 You should use a different site each time you inject PegIntron™ to avoid soreness at any
 461 one site. Do not inject PegIntron™ into an area where the skin is irritated, red, bruised,
 462 infected, or has scars, stretch marks, or lumps.

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- a. Clean the skin where the injection is to be given with the second alcohol swab provided,
 and wait for the area to dry.
- b. Remove the **outer** cap from the needle (**Figure 6a**). There may be some liquid around the
 yellow inner needle cap (**Figure 6b**). This is normal.



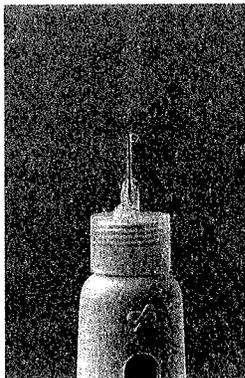
471
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Figure 6a

Figure 6b

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



478
 479

Figure 6c

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

- With your other hand, pinch the skin in the area you have cleaned for injection.



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- 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.
 - 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.



489

490 **Figure 7**

491

492 **c. Gently press the injection site with a small bandage or sterile gauze if necessary for a**
 493 **few seconds but do not massage the injection site. If there is bleeding, cover with an**
 494 **adhesive bandage. DO NOT RECAP THE NEEDLE and DO NOT REUSE the**
 495 **REDIPEN®.**

496

497 **How do I Dispose of the REDIPEN®?**

498 Discard the REDIPEN® and needle and any solution remaining in the REDIPEN® in a sharps
 499 container or other puncture-resistant container like a metal coffee can. DO NOT use glass or
 500 clear plastic containers. Ask your health care provider how to dispose of a full container.
 501 Always keep the container out of reach of children.

502

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

506

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

508

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

510 **DATE 06/08**



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