

1 052907.Redipen Med Guide-final draft

2  
3 **MEDICATION GUIDE**

4 **PegIntron™ Redipen® Single-dose Delivery System**  
5 **(Peginterferon alfa-2b)**

6  
7 **Including appendix with instructions for using PegIntron™ Redipen® Single-dose**  
8 **Delivery System**

9  
10 Read this Medication Guide carefully before you start taking PegIntron™ (**Peg In-tron**) or  
11 PegIntron™/REBETOL® (**REB-eh-tole**) combination therapy. Read the Medication Guide  
12 each time you refill your prescription because there may be new information. The  
13 information in this Medication Guide does not take the place of talking with your health care  
14 provider (doctor, nurse, nurse practitioner, or physician's assistant).

15  
16 If you are taking PegIntron/REBETOL combination therapy, also read the Medication Guide  
17 for REBETOL (ribavirin, USP) Capsules.

18  
19 **What is the most important information I should know about PegIntron and**  
20 **PegIntron/REBETOL combination therapy?**

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

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

41  
42  
43 If you are taking PegIntron or PegIntron/REBETOL therapy you should call your  
44 health care provider immediately if you develop any of these symptoms:

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45  
46 **New or worsening mental health problems, such as thoughts about killing or hurting**  
47 **yourself or others, trouble breathing, chest pain, severe stomach or lower back pain,**  
48 **bloody diarrhea or bloody bowel movements, high fever, bruising, bleeding, or**  
49 **decreased vision.**

50  
51 The most serious possible side effects of PegIntron and PegIntron/REBETOL therapy  
52 include:

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

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

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

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

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

89

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

92  
93 *For other possible side effects, see "What are the possible side effects of PegIntron and*  
94 *PegIntron/REBETOL" in this Medication Guide.*

95  
96 **What is PegIntron and PegIntron/REBETOL combination therapy?**

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

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

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

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

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

113 Do not take PegIntron or PegIntron/REBETOL therapy if you:

- 114 • are pregnant, planning to get pregnant during treatment or during the 6 months after  
115 treatment, or breast-feeding
- 116  
117 • are a male patient with a female sexual partner who is pregnant, or plans to become  
118 pregnant at any time while you are being treated with REBETOL, or during the 6  
119 months after your treatment has ended
- 120  
121 • have hepatitis caused by your immune system attacking your liver (autoimmune  
122 hepatitis) or unstable liver disease
- 123  
124 • had an allergic reaction to another alpha interferon or are allergic to any of the  
125 ingredients in PegIntron or REBETOL Capsules. If you have any doubts, ask your  
126 health care provider.
- 127  
128 • Do not take PegIntron/REBETOL combination therapy if you have abnormal red  
129 blood cells such as sickle-cell anemia or thalassemia major.

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

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

153

154

#### 155 **How should I take PegIntron or PegIntron/REBETOL?**

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

168

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

174

175 If you miss a dose of the PegIntron product, take the missed dose as soon as possible during  
 176 the same day or the next day, then continue on your regular dosing schedule. If several days  
 177 go by after you miss a dose, check with your health care provider about what to do. Do not

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178 double the next dose or take more than one dose a week without talking to your health care  
179 provider. Call your health care provider right away if you take more than your prescribed  
180 PegIntron dose. Your health care provider may wish to examine you more closely, and take  
181 blood for testing.

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

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

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

192  
193 **What should I avoid while taking PegIntron or PegIntron/REBETOL therapies?**

- 194 • If you are pregnant do not start taking PegIntron/REBETOL combination therapy.  
195 • Avoid becoming pregnant while taking PegIntron or PegIntron/REBETOL.

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

- 205  
206 • Do not breast-feed your baby while taking PegIntron.

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

210  
211 **Possible, serious side effects include:**

212 **Mental health problems including suicide, blood problems, heart problems, body organ**  
213 **problems.** See "What is the most important information I should know about PegIntron and  
214 PegIntron/REBETOL combination therapy?"

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

218  
219 **New or worsening autoimmune disease.** Some patients taking PegIntron or  
220 PegIntron/REBETOL develop autoimmune diseases (a condition where the body's immune  
221 cells attack other cells or organs in the body), including rheumatoid arthritis, systemic lupus

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222 erythematosus, and psoriasis. In some patients who already have an autoimmune disease, the  
223 disease worsens on PegIntron and PegIntron/REBETOL combination therapy.

224

225 Common but less serious side effects include:

226

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

233

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

236

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

238

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

242

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

245

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

250

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

253

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

256

257 **General advice about prescription medicines:**

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

263

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

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266

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

268

269 **DATE 05/07**

270

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

272

273 The PegIntron Redipen system is for a single use, by one person only, once a week. The  
 274 Redipen must not be shared. Use only the injection needle provided in the packaging for the  
 275 PegIntron Redipen system. If you have problems with the Redipen system or the  
 276 PegIntron™ solution, you should contact your health care provider or pharmacist.

277

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

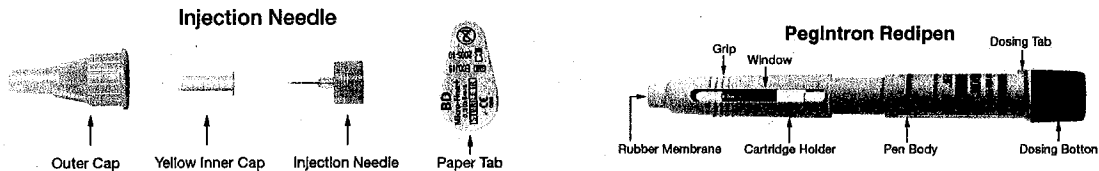
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284

285 **How to Use the PegIntron Redipen Single-dose Delivery System.**

286

287



288

289

290

291 **Storing PegIntron**

292 PegIntron Redipen should be stored in the refrigerator at 2°C to 8°C (36°F to 46°F); avoid  
 293 exposure to heat. After mixing, the PegIntron solution should be used immediately but may  
 294 be stored in the refrigerator up to 24 hours at 2°C to 8°C (36°F - 46°F). The solution  
 295 contains no preservatives. DO NOT FREEZE.

296

297 **Preparation**

298

- 299 1. Find a clean, well-lit, non-slip flat working surface and assemble all of the supplies you  
 300 will need for an injection. All of the supplies you will need are in the PegIntron Redipen  
 301 package. The package contains:
- 302 ■ a PegIntron Redipen single-dose delivery system
  - 303 ■ one disposable needle
  - 304 ■ two alcohol swabs, and

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- 305       ▪ Dosing tray; (The dosing tray is the bottom half of the Redipen package.)  
306  
307       2. Take the PegIntron Redipen out of the refrigerator and allow the medicine to come to  
308       room temperature. Before removing the Redipen from the carton, check the expiration  
309       date printed on the PegIntron Redipen® carton to make sure that the expiration date has  
310       not passed. Do not use if the expiration date has passed.  
311       3. After taking the PegIntron Redipen out of the carton, look in the window of the Redipen  
312       and make sure the PegIntron in the cartridge holder window is a white, to off white tablet  
313       that is whole, or in pieces, or powdered.  
314       4. Wash your hands thoroughly with soap and water, rinse, and towel dry. It is important  
315       to keep your work area, your hands, and the injection site clean to minimize the risk of  
316       infection.

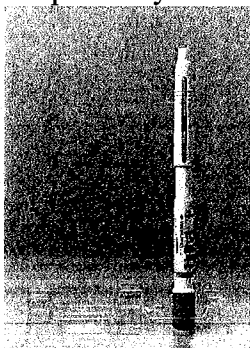
317  
318       **1. Mix the Drug**

319  
320       **Key points:**

321  
322       **Before you mix the PegIntron, make sure it is at room temperature. It is important that**  
323       **you keep the PegIntron Redipen UPRIGHT (Dosing Button down) as shown in Figure**  
324       **1.**

325  
326       a. Hold the PegIntron Redipen **UPRIGHT (Figure 1a)** in the dosing tray on a hard, flat,  
327       non-slip surface with the dosing button **down**. You may want to hold the Redipen using  
328       the grip.

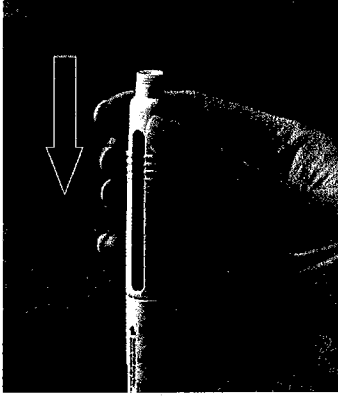
329  
330       b. To mix the powder and the liquid, keep the Redipen® upright in the dosing tray and  
331       press the top half of the Redipen downward toward the hard, flat, non-slip surface **until**  
332       **you hear the click** (Figure 1b). Once you've heard the click, you will notice in the  
333       window that both dark stoppers are now touching. The dosing button should be flush with  
334       the pen body.



335       **Figure 1a**  
336  
337



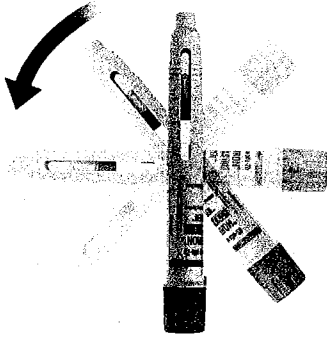




338  
339 **Figure 1b**

340  
341 c. Wait several seconds for the powder to completely dissolve.

342  
343  
344 **d. Gently turn the PegIntron Redipen upside down twice (Figure 2). To avoid**  
345 **excessive foaming, DO NOT SHAKE.**

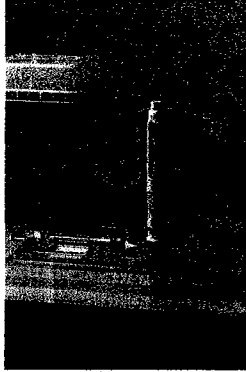


346  
347 **Figure 2**

348  
349 e. Keep the PegIntron Redipen **UPRIGHT**, with the dosing button down. Then, look  
350 through the Redipen window to see that the mixed PegIntron solution is completely  
351 dissolved. The solution should be clear and colorless **before use**. Before attaching the  
352 needle, it is normal to see some small bubbles in the Redipen window, near the top of the  
353 solution. Do not use the solution if it is discolored, or not clear, or if particulates are  
354 present.

355 **f. Place the PegIntron Redipen back into the dosing tray provided in the packaging**  
356 **(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.
- b. Remove the protective paper tab from the injection needle, but do NOT remove either the outer cap or the yellow inner cap from the injection needle. Keeping the PegIntron Redipen UPRIGHT in the dosing tray, FIRMLY push the injection needle straight into the Redipen rubber membrane, and screw it firmly in place, in a clockwise direction (Figure 4). Remember to leave the needle caps in place when you attach the needle to the Redipen. Pushing the needle through the rubber membrane, “primes” the needle and allows the extra liquid and air in the pen to be removed.



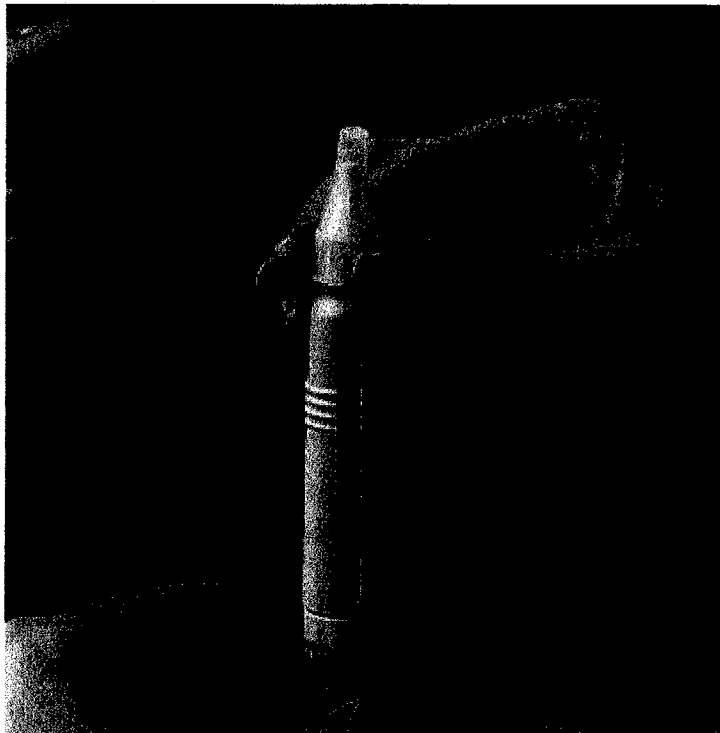


Figure 4

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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.

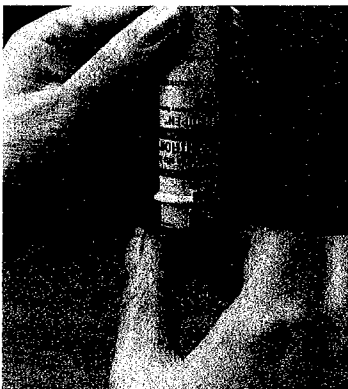
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### 3. Dialing the Dose

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**).

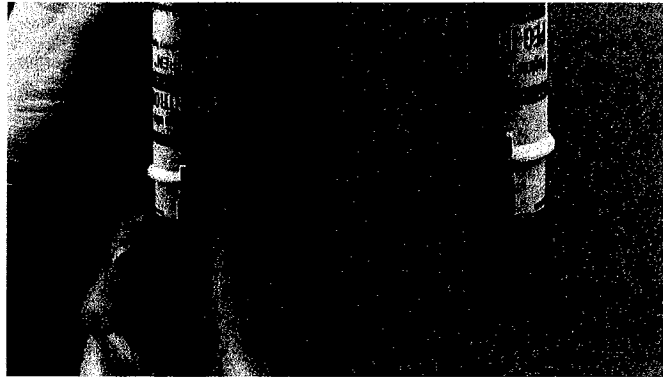


Figure 5b

Figure 5c

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401

402  
403  
404

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

408

#### 4. Injecting the PegIntron Dose

##### Choosing an Injection Site

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

415

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

419

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

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

424

425

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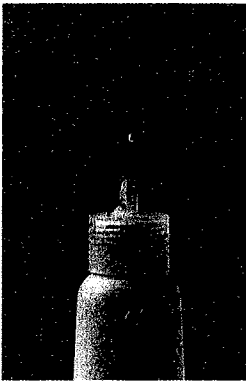
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427  
428 **Figure 6a**429 **Figure 6b**

430  
431 c. Once the injection site is dry, remove the **yellow** inner needle cap (**Figure 6c**). You are  
432 now ready to inject.  
433

434  
435 **Figure 6c**

436  
437 **d. Hold the PegIntron Redipen with your fingers wrapped around the pen body barrel**  
438 **and your thumb on the dosing button (Figure 7).**

- 439
- 440 • With your other hand, pinch the skin in the area you have cleaned for injection.
  - 441 • Insert the needle into the pinched skin at an angle of 45° to 90°.
  - 442 • Press the dosing button down slowly and firmly until you can't push it any further.
  - 443 • Keep your thumb pressed down on the dosing button for an additional 5 seconds to ensure that you get the complete dose.
  - 444 • Remove the needle from your skin.





445  
446 **Figure 7**

447  
448 **e. Gently press the injection site with a small bandage or sterile gauze if necessary for a**  
449 **few seconds but do not massage the injection site. If there is bleeding, cover with an**  
450 **adhesive bandage. DO NOT RECAP THE NEEDLE and DO NOT REUSE the Redipen.**

451  
452 **How do I Dispose of the Redipen?**

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

457  
458 **After 2 hours, check the injection site for redness, swelling, or tenderness.**  
459 **If you have a skin reaction and it doesn't clear up in a few days, contact**  
460 **your health care provider.**

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