

1 032408.final draft Med Guide powder for injection

2 **MEDICATION GUIDE**

3 **PegIntron®**

4 **Peginterferon alfa-2b**

5  
6 **Including appendix with instructions for using PegIntron® Powder for Injection**

7  
8 Read this Medication Guide carefully before you start taking PegIntron (**Peg In-tron**) or  
9 PegIntron/REBETOL (**REB-eh-tole**) combination therapy. Read the Medication Guide each  
10 time you refill your prescription because there may be new information. The information in  
11 this Medication Guide does not take the place of talking with your health care provider  
12 (doctor, nurse, nurse practitioner, or physician's assistant).

13  
14 **If you are taking PegIntron/REBETOL combination therapy, also read the Medication**  
15 **Guide for REBETOL (ribavirin, USP) Capsules.**

16  
17 **What is the most important information I should know about PegIntron and**  
18 **PegIntron/REBETOL combination therapy?**

19  
20 PegIntron (peginterferon) is a treatment for some people who are infected with hepatitis C  
21 virus. However, PegIntron and PegIntron/REBETOL combination 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 or PegIntron/REBETOL combination therapy. If you begin treatment you will  
25 need to see your health care provider regularly for medical examinations and lab tests to  
26 make sure your 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**  
30 **combination therapy. You must not become pregnant while either you or your partner**  
31 **are being treated with the combination PegIntron/REBETOL therapy, or for 6 months**  
32 **after stopping therapy. Men and women should use birth control while taking the**  
33 **combination therapy and for 6 months afterwards. If you or your partner are being**  
34 **treated and you become pregnant either during treatment or within 6 months of**  
35 **stopping treatment, call your health care provider right away. There is a Ribavirin**  
36 **Pregnancy Registry that collects information about pregnancy outcomes in female**  
37 **patients and female partners of male patients exposed to ribavirin. You or your**  
38 **healthcare provider are encouraged to contact the Registry at 1-800-593-2214.**

39  
40 **If you are taking PegIntron or PegIntron/REBETOL therapy you should call your**  
41 **health care provider immediately if you develop any of these symptoms:**

42  
43 **New or worsening mental health problems such as thoughts about killing or hurting**  
44 **yourself or others, trouble breathing, chest pain, severe stomach or lower back pain,**  
45 **bloody diarrhea or bloody bowel movements, high fever, bruising, bleeding, or**  
46 **decreased vision.**



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

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

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

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

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

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

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

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.

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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

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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

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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

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

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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:**

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)

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#### 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 time.

160 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<sup>®</sup> 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  
 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.

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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.

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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.

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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.

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

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- If you are pregnant do not start taking PegIntron/REBETOL combination therapy.

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- Avoid becoming pregnant while taking PegIntron or PegIntron/REBETOL.

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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 become**

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**pregnant during treatment or during the 6 months after treatment with**

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**PegIntron/REBETOL combination therapy, immediately report the pregnancy to your**

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**health care provider. You or your health care provider should call 1-800-593-2214. By**

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calling this number, information about you and/or your partner will be added to a pregnancy

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registry that will be used to help you and your health care provider make decisions about

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your treatment for hepatitis in the future. You, your partner and/or your health care provider

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will be asked to provide follow-up information on the outcome of the pregnancy.

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- Do not breast-feed your baby while taking PegIntron.

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

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**Possible, serious side effects include:**

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

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

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

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

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- 229 • **Flu-like symptoms.** Most patients who take PegIntron or PegIntron/REBETOL  
 230 therapy have "flu-like" symptoms (headache, muscle aches, tiredness and fever).  
 231 Some of these symptoms (fever, headache) usually lessen after the first few weeks of  
 232 therapy. You can reduce some of these symptoms by injecting your PegIntron dose at  
 233 bedtime. Over-the-counter pain and fever reducers, such as acetaminophen or  
 234 ibuprofen, can be used to prevent or reduce the fever and headache.  
 235
- 236 • **Extreme fatigue (tiredness).** Many patients become extremely tired while on  
 237 PegIntron or PegIntron/REBETOL combination therapy.  
 238
- 239 • **Appetite problems.** Nausea, loss of appetite, and weight loss occur commonly.  
 240
- 241 • **Thyroid problems.** Some patients develop changes in the function of their thyroid.  
 242 Symptoms of thyroid changes include the inability to concentrate, feeling cold or hot  
 243 all the time, a change in your weight and changes to your skin.  
 244
- 245 • **Blood sugar problems.** Some patients develop problems with the way their body  
 246 controls their blood sugar and may develop high blood sugar or diabetes.  
 247
- 248 • **Skin reactions.** Redness, swelling, and itching are common at the site of injection.  
 249 If after several days these symptoms do not disappear contact your health care  
 250 provider. You may get a rash during therapy. If this occurs, your health care  
 251 provider may recommend medicine to treat the rash.  
 252
- 253 • **Hair thinning.** Hair thinning is common during PegIntron and PegIntron/REBETOL  
 254 treatment. Hair loss stops and hair growth returns after therapy is stopped.  
 255

256 These are not all of the side effects of PegIntron or PegIntron/REBETOL combination  
 257 therapy. Your health care provider or pharmacist can give you a more complete list.  
 258

259 **Call your doctor for medical advice about side effects. You may report side effects to FDA at**  
 260 **1-800-FDA-1088.**  
 261

262 **General advice about prescription medicines:**

263 Medicines are sometimes prescribed for purposes other than those listed in a Medication  
 264 Guide. If you have any concerns about PegIntron, ask your health care provider. Your health  
 265 care provider or pharmacist can give you information about PegIntron that was written for  
 266 health care professionals. Do not use PegIntron for a condition for which it was not  
 267 prescribed. Do not share this medication with other people.  
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269 **If you are taking PegIntron/REBETOL combination therapy, also read the Medication**  
 270 **Guide for REBETOL (ribavirin, USP) Capsules.**  
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272 *This Medication Guide has been approved by the U.S. Food and Drug Administration.*

273 **Revised May 2007**  
 274



275 **How do I prepare and inject the PegIntron Dose?**

276 Before you inject PegIntron, the powder must be mixed with **0.7 mL** of the supplied  
 277 DILUENT for PegIntron, Sterile Water for Injection (diluent). You should carefully  
 278 follow the directions given to you by your health care provider.

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 280 The vial of mixed PegIntron should be used immediately. **DO NOT** prepare more than one  
 281 vial at a time. If you don't use the vial of the prepared solution right away, it must be  
 282 stored in a refrigerator and used within 24 hours.

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 284 **Storing PegIntron**

285 PegIntron Powder should be stored at room temperature (25 ° C, 77°F); avoid exposure to  
 286 heat. After mixing, the PegIntron solution should be used immediately but may be stored  
 287 in the refrigerator up to 24 hours. The solution contains no preservatives. **DO NOT**  
 288 FREEZE.

289 **Preparing the PegIntron solution:**

- 290  
 291 1. Find a clean, well-lit, non-slip flat working surface and assemble all of the supplies  
 292 you will need for an injection. All of the supplies you will need for an injection are  
 293 in the PegIntron Powder for Injection package. The package contains:  
 294     ▪ a vial of PegIntron powder  
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 296     ▪ a 1.25 mL vial of DILUENT  
 297  
 298     ▪ 2 disposable syringes, and  
 299  
 300     ▪ alcohol swabs  
 301  
 302 2. Check the date printed on the PegIntron carton to make sure that the expiration date  
 303 has not passed. Remove one vial and look at the contents. The PegIntron in the vial  
 304 should appear as a white to off-white tablet-like solid that is whole/in pieces or as a  
 305 loose powder.

306  
 307 If you have already mixed the PegIntron solution and it has been stored properly in the  
 308 refrigerator, take it out of the refrigerator and allow the solution to come to room  
 309 temperature.

- 310  
 311 3. Wash your hands thoroughly with soap and water, rinse and towel dry. It is important  
 312 to keep your work area, your hands and injection site clean to minimize the risk of  
 313 infection.

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 315 The disposable syringes have needles that are already attached and cannot be removed.  
 316 Each syringe has a clear plastic safety sleeve that is pulled over the needle for disposal  
 317 after use. The safety sleeve should remain tight against the flange while using the  
 318 syringe and moved over the needle only when ready for disposal. **Figure A.**

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The syringes and needles are for single use only.

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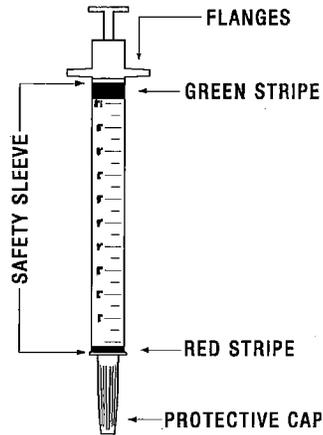


Figure A

4. Remove the protective wrapper from ONE of the syringes provided and use for the following steps 5-7. Make sure that the syringe safety sleeve is sitting against the flange. (see **Figure A**).
5. Remove the protective plastic cap from the tops of both the supplied DILUENT and the PegIntron vials. Clean the rubber stopper on the top of both vials with an alcohol swab.
6. Carefully remove the protective cap straight off of the needle to avoid damaging the needle point. Fill the syringe with air by pulling the plunger to 0.7 mL (**Figure B**). Hold the DILUENT vial upright. Do not touch the cleaned top of the vial with your hands (**Figure C**). Insert the needle through the center of the rubber stopper of the DILUENT vial, and inject the air from the syringe into the vial (**Figure D**). Turn the vial upside down and make sure the tip of the needle is in the liquid. Withdraw only 0.7 mL of DILUENT by pulling the plunger back to the 0.7 mL mark on the side of the syringe (**Figure E**). Remove the needle from the vial (**Figure F**). **Discard the remaining DILUENT.**

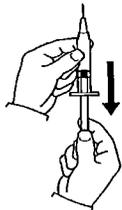


Figure B

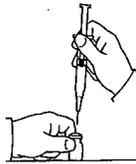


Figure C

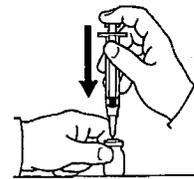


Figure D

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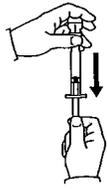


Figure E

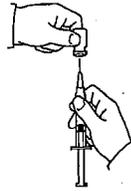


Figure F

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Figure G



Figure H

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7. Insert the needle through the center of the rubber stopper of the PegIntron vial, and place the needle tip against the glass wall of the vial (Figure G). SLOWLY inject the 0.7 mL DILUENT so that the stream of DILUENT runs down the side of the vial. To prevent bubbles from forming, DO NOT AIM THE STREAM of diluent directly on the tablet-like SOLID or POWDER in the bottom of the vial. Remove the needle from the vial.

Firmly grasp the safety sleeve and pull it over the exposed needle until you hear a click. The green stripe on the safety sleeve will completely cover the red stripe on the needle. (See Figure O in the section: "Injecting the PegIntron dose.") Discard the syringe and needle in the puncture proof container.

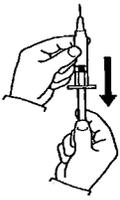
8. GENTLY swirl the vial in a gentle circular motion (Figure H), until the PegIntron is completely dissolved. DO NOT SHAKE the vial. If any powder remains undissolved in the vial, gently turn the vial upside down until all of the powder is dissolved. It is not unusual for the solution to appear cloudy or bubbly for a few minutes. If air bubbles do form, wait until the solution has settled and all bubbles have risen to the top before withdrawing your dose from the vial.

9. After the solution has settled and is completely dissolved it should be clear, colorless and without particles, but there may be a ring of foam or bubbles on the surface, this is normal. Do not use it if you see particles or the color is not correct.

10. After the PegIntron powder is dissolved but before you withdraw your dose, clean the rubber stopper again with an alcohol swab.

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11. Unwrap the second syringe provided. You will use it to give yourself the injection. Carefully remove the protective cap from the needle and fill the syringe with air by pulling the plunger to the number on the side of the syringe (mL) that corresponds to your prescribed dose (**Figure J**). Hold the PegIntron vial upright. **DO NOT** touch the cleaned top of the vial with your hands (**Figure K**). Insert the needle into the vial containing the PegIntron solution and inject the air into the center of the vial (**Figure L**).



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Figure J

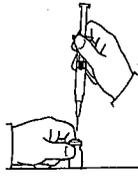


Figure K

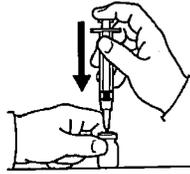
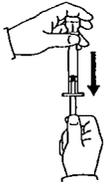


Figure L

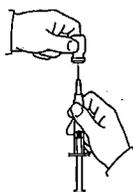
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12. Turn the PegIntron vial upside down. Be sure the tip of the needle is in the PegIntron solution. While holding the vial and syringe with one hand slowly pull the plunger back to withdraw the exact amount of PegIntron into the syringe your health care provider told you to use (**Figure M**).



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Figure M

13. Remove the needle from the vial (**Figure N**) and check for air bubbles in the syringe. If you see any bubbles, hold the syringe with the needle pointing up and gently tap the syringe until the bubbles rise. Then push the plunger in slowly until the bubbles disappear.



423 Figure N

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426 **Injecting the PegIntron Dose**427 **Selecting the Site for Injection.**

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

432

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

436

437 14. Clean the skin where the injection is to be given with an alcohol swab, and wait for  
 438 the area to dry. Remove the protective cap from the needle. Make sure the safety sleeve of  
 439 the syringe is pushed firmly against the syringe flange so that the needle is fully exposed  
 440 (see **Figure A**).

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442 15. With one hand, pinch a 2-inch fold of loose skin. With your other hand, pick up the  
 443 syringe and hold it like a pencil. Position the bevel of the needle facing up and insert the  
 444 needle approximately  $\frac{1}{4}$  inch into the pinched skin at approximately a 45 to 90 degree  
 445 angle with a quick dart-like thrust. After the needle is in, remove the hand that you used to  
 446 pinch your skin and use it to hold the syringe barrel. Pull the plunger of the syringe back  
 447 very slightly. If blood comes into the syringe, the needle has entered a blood vessel. **Do**  
 448 **not inject.** Withdraw the needle and discard the syringe as outlined in step 17. Repeat the  
 449 above steps with a new vial to prepare a new syringe and inject the medicine at a new site.  
 450 If no blood is present in the syringe, inject the medicine by gently pressing the plunger all  
 451 the way down the syringe barrel.

452

453 16. Hold an alcohol swab near the needle and pull the needle straight out of the skin.  
 454 Press the alcohol swab over the injection site for several seconds. Do not massage the  
 455 injection site. If there is bleeding, cover it with a bandage.

456

457 17. After injecting your dose, firmly grasp the safety sleeve and pull it over the exposed  
 458 needle until you hear a click, and the green stripe on the safety sleeve covers the red stripe  
 459 on the needle (**Figure O**). Discard the syringe and needle in the Sharp's container supplied  
 460 to you.

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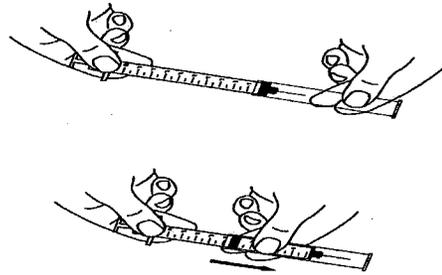


Figure O

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

**How do I dispose of the used syringes and needles?**

Discard used safety lock syringes and needles in a Sharp's container or other puncture proof container like a coffee can. **DO NOT USE** glass or clear plastic containers. Your health care provider or nurse will tell you how to dispose a full container. Always keep the container out of reach of children.

Manufactured by: Schering Corporation, Kenilworth, NJ 07033 USA

**DATE 3/08**

1 **032408.final draft Med Guide Redipen**  
2 **MEDICATION GUIDE**  
3 **PegIntron™ Redipen® Single-dose Delivery System**  
4 **(Peginterferon alfa-2b)**

5  
6 **Including appendix with instructions for using PegIntron™ Redipen® Single-dose**  
7 **Delivery System**

8  
9 Read this Medication Guide carefully before you start taking PegIntron™ (**Peg In-tron**) or  
10 PegIntron™/REBETOL® (**REB-eh-tole**) combination therapy. Read the Medication Guide  
11 each time you refill your prescription because there may be new information. The  
12 information in this Medication Guide does not take the place of talking with your health care  
13 provider (doctor, nurse, nurse practitioner, or physician's assistant).

14  
15 If you are taking PegIntron/REBETOL combination therapy, also read the Medication Guide  
16 for REBETOL (ribavirin, USP) Capsules.

17  
18 **What is the most important information I should know about PegIntron and**  
19 **PegIntron/REBETOL combination therapy?**

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

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

40  
41 **If you are taking PegIntron or PegIntron/REBETOL therapy you should call your**  
42 **health care provider immediately if you develop any of these symptoms:**

43  
44 **New or worsening mental health problems, such as thoughts about killing or hurting**  
45 **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 may  
64 cause patients to develop mood or behavioral problems. These can include irritability (getting  
65 easily upset) and depression (feeling low, feeling bad about yourself, or feeling hopeless).  
66 Some patients may have aggressive behavior. Former drug addicts may fall back into drug  
67 addiction or overdose. Some patients think about hurting or killing themselves or other  
68 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 may  
74 develop problems with their heart, including low blood pressure, fast heart rate, and very  
75 rarely, heart attacks. Tell your health care provider if you have had any heart problems in the  
76 past.

77

78 **Blood problems.** PegIntron and PegIntron/REBETOL therapies commonly lower two types  
79 of blood cells (white blood cells and platelets). In some patients, these blood counts may fall  
80 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. Cases of weakness, loss of coordination, and numbness  
90 due to stroke have been reported in patients taking PegIntron, including patients with few or  
91 no reported risk factors for stroke.

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

- 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

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

121

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

124

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

126

127

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

131

- depression or anxiety
- sleep problems
- high blood pressure
- previous heart attack, or other heart problems

132

133

134

135

136

137

- 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 delivery  
172 system. See the attached appendix for detailed instructions for preparing and giving a dose of  
173 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  
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  
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 have  
228 "flu-like" symptoms (headache, muscle aches, tiredness, and fever). Some of these symptoms

229 (fever, headache) usually lessen after the first few weeks of therapy. You can reduce some of  
230 these symptoms by injecting your PegIntron dose at bedtime. Over-the-counter pain and  
231 fever reducers, such as acetaminophen or ibuprofen, can be used to prevent or reduce the  
232 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 medicine  
249 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 Call your doctor for medical advice about side effects. You may report side effects to FDA at  
258 1-800-FDA-1088.

259

#### 260 **General advice about prescription medicines:**

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

266

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

269

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

271

272

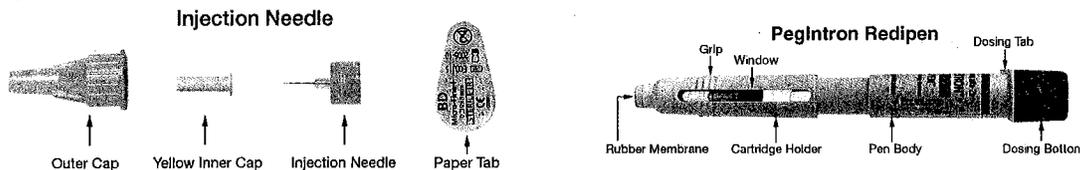
#### 273 **How do I prepare and inject the PegIntron Redipen Dose?**

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

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

285  
 286  
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 289

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



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 297  
 298

### Storing PegIntron

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

### Preparation

- 300  
 301 1. Find a clean, well-lit, non-slip flat working surface and assemble all of the supplies you  
 302 will need for an injection. All of the supplies you will need are in the PegIntron Redipen  
 303 package. The package contains:  
 304     ▪ a PegIntron Redipen single-dose delivery system  
 305     ▪ one disposable needle  
 306     ▪ two alcohol swabs, and  
 307     ▪ Dosing tray; (The dosing tray is the bottom half of the Redipen package.)  
 308  
 309 2. Take the PegIntron Redipen out of the refrigerator and allow the medicine to come to  
 310 room temperature. Before removing the Redipen from the carton, check the expiration  
 311 date printed on the PegIntron Redipen carton to make sure that the expiration date has not  
 312 passed. Do not use if the expiration date has passed.

- 313 3. After taking the PegIntron Redipen out of the carton, look in the window of the Redipen  
314 and make sure the PegIntron in the cartridge holder window is a white, to off white tablet  
315 that is whole, or in pieces, or powdered.
- 316 4. Wash your hands thoroughly with soap and water, rinse, and towel dry. It is important  
317 to keep your work area, your hands, and the injection site clean to minimize the risk of  
318 infection.

319

320 **1. Mix the Drug**

321

322 **Key points:**

323

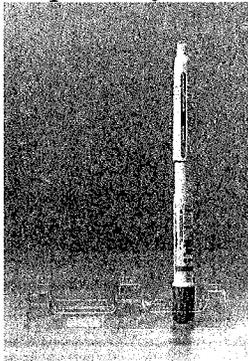
324 **Before you mix the PegIntron, make sure it is at room temperature. It is important that**  
325 **you keep the PegIntron Redipen UPRIGHT (Dosing Button down) as shown in Figure**  
326 **1.**

327

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

331

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

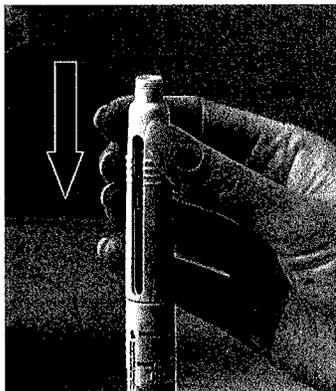


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338

339 **Figure 1a**

339



340

341 **Figure 1b**

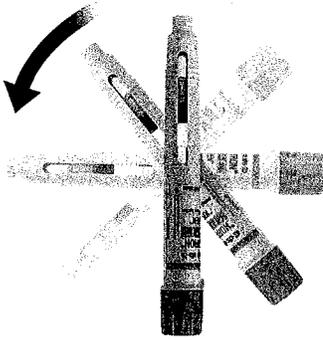
342

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

344

345

346 **d. Gently turn the PegIntron Redipen upside down twice (Figure 2). To avoid**  
347 **excessive foaming, DO NOT SHAKE.**



348

349 **Figure 2**

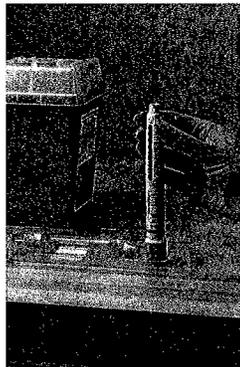
350

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

357

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

360



**Figure 3**

361

362

363

364

365

366

367

368

## 2. Attach the Needle

369

370

a. Wipe the rubber membrane of the PegIntron Redipen with one alcohol swab.

371

372

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.

373

374

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378

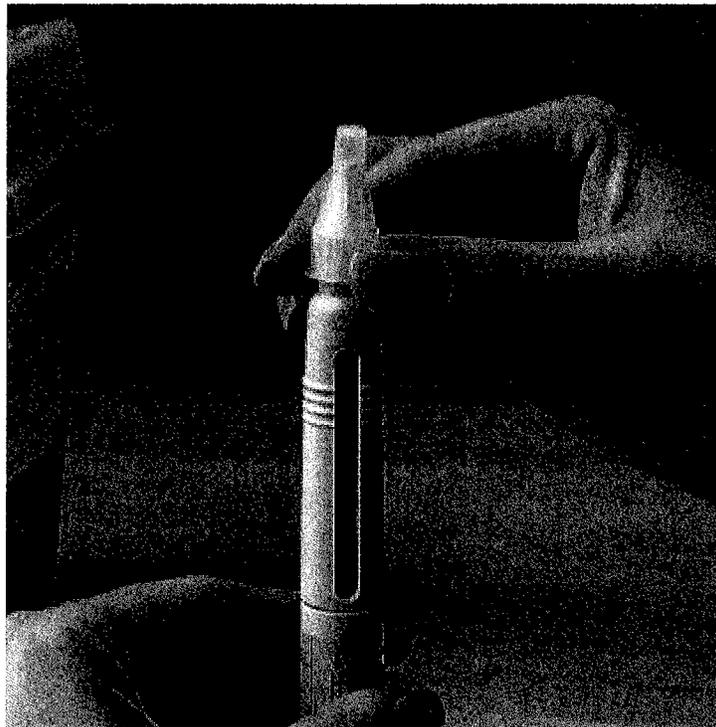


Figure 4

379

380

381

382

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.

383

384

385

## 3. Dialing the Dose

386

387

a. **Remove the PegIntron Redipen from the dosing tray (Figure 5a).**

388

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

389

390

391

392

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

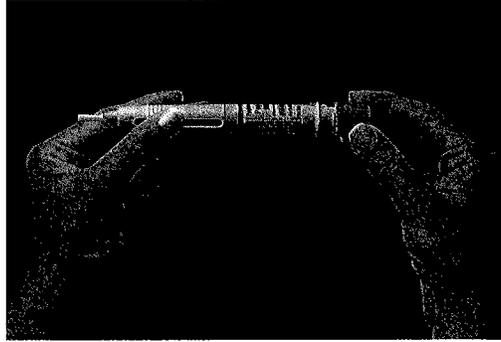


Figure 5a

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**).

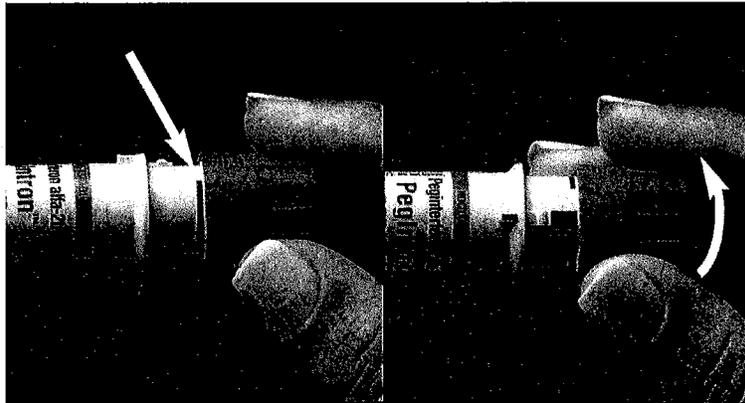


Figure 5b

Figure 5c

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.

#### 4. Injecting the PegIntron Dose

##### Choosing an Injection Site

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.

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

- 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  
426

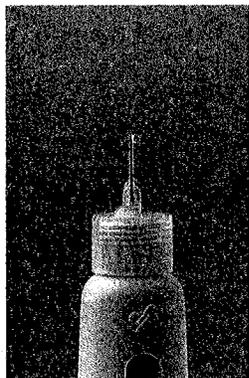


427

428 **Figure 6a****Figure 6b**

429

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



433

434 **Figure 6c**

435

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

438

439

440

441

442

443

- 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.
- 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.