

1 **MEDICATION GUIDE**

2 **PEGASYS**

3 **(peginterferon alfa-2a)**

4 **Rx only**

5 Before you start taking PEGASYS (PEG-ah-sis), alone or in combination with
6 COPEGUS (Co-PEG-UHS), please read this Medication Guide carefully. Read this
7 Medication Guide each time you refill your prescription in case new information has
8 been added and make sure the pharmacist has given you the medicine your healthcare
9 provider prescribed for you. Reading the information in this Medication Guide does not
10 take the place of talking with your healthcare provider.

11 *If you are taking PEGASYS in combination with COPEGUS, you should also read the*
12 *Medication Guide for COPEGUS (ribavirin, USP) Tablets.*

13 **What is the most important information I should know about PEGASYS**
14 **therapy?**

15 PEGASYS, taken alone or in combination with COPEGUS, is a treatment for some
16 people who are infected with hepatitis C virus. PEGASYS taken alone is a treatment for
17 some people who are infected with the hepatitis B virus. However, PEGASYS and
18 COPEGUS can have serious side effects that may cause death in rare cases. Before
19 starting PEGASYS therapy, you should talk with your healthcare provider about the
20 possible benefits and the possible side effects of treatment, to decide if either of these
21 treatments is right for you. If you begin treatment you will need to see your healthcare
22 provider regularly for examinations and blood tests to make sure your treatment is
23 working and to check for side effects.

24 The most serious possible side effects of PEGASYS taken alone or in combination with
25 COPEGUS include:

26 **Problems with Pregnancy:**

27 **Taking PEGASYS in combination with COPEGUS tablets can cause death, serious**
28 **birth defects or other harm to your unborn child. Therefore, if you are pregnant or**
29 **your partner is pregnant or plans to become pregnant, do not take**
30 **PEGASYS/COPEGUS combination therapy. Female patients and female partners**
31 **of male patients being treated with PEGASYS/COPEGUS combination therapy**
32 **must not become pregnant during treatment and for 6 months after treatment has**
33 **stopped. During this time, you must have pregnancy tests that show you are not**
34 **pregnant. You must also use two effective forms of birth control during therapy and**
35 **for 6 months after stopping therapy. Male patients should use a condom with**
36 **spermicide as one of the two forms.** You must use birth control even if you believe that
37 you are not fertile or that your fertility is low. You should talk to your healthcare provider
38 about birth control for you and your partner.

39 **If you are pregnant, you or your male partner must not take PEGASYS/COPEGUS**
40 **combination therapy. If you or your partner are being treated and you become**

41 **pregnant either during treatment or within 6 months of stopping treatment, call**
42 **your healthcare provider right away.**

43 If you or a female sexual partner becomes pregnant, you should tell your healthcare
44 provider. There is a Ribavirin Pregnancy Registry that collects information about
45 pregnancy outcomes of female patients and female partners of male patients exposed to
46 ribavirin. You or your healthcare provider are encouraged to contact the Registry at 1-
47 800-593-2214.

48 **Mental health problems and suicide:**

49 PEGASYS and PEGASYS/COPEGUS combination therapy may cause some patients to
50 develop mood or behavioral problems. Signs of these problems include irritability
51 (getting easily upset), depression (feeling low, feeling bad about yourself or feeling
52 hopeless), and anxiety. Some patients may have aggressive behavior. Former drug addicts
53 may fall back into drug addiction or overdose. Some patients think about hurting or
54 killing themselves or other people and some have killed (suicide) or hurt themselves or
55 hurt other people. You must tell your healthcare provider if you are being treated for a
56 mental illness or have a history of mental illness, including depression and suicidal
57 behavior or if you are or have ever been addicted to drugs or alcohol. Call your
58 healthcare provider immediately if you develop any of these problems while on
59 PEGASYS treatment.

60 **Heart problems:**

61 Some patients taking PEGASYS or PEGASYS/COPEGUS therapies may develop
62 problems with their heart, including low blood pressure, fast heart rate, and very rarely,
63 heart attacks. Tell your healthcare provider if you have had any heart problems in the
64 past.

65 **Blood problems:**

66 Many patients taking PEGASYS have had a drop in the number of their white blood cells
67 and their platelets. If the numbers of these blood cells are too low, you could be at risk for
68 serious infections or bleeding.

69 COPEGUS causes a decrease in the number of your red blood cells (anemia). This can be
70 dangerous, especially for patients who already have heart or circulatory (cardiovascular)
71 problems. If you have or have ever had any cardiovascular problems, talk with your
72 healthcare provider before taking the combination of PEGASYS and COPEGUS.

73 **Liver problems:**

74 Infrequently, some patients with hepatitis C and liver scarring can develop sudden severe
75 worsening (failure) of their liver disease while taking PEGASYS. Patients infected with
76 both the hepatitis C virus and HIV can have an increased chance of having liver failure
77 during PEGASYS treatment.

78 Some patients taking PEGASYS for hepatitis B have had a rise in a blood test that
79 measures liver inflammation. If you have a rise in this blood test, your liver may need to
80 be watched more closely with additional blood tests.

81 **Infections:**

82 Some patients taking interferon have had serious infections. Sometimes these infections
83 have been fatal. If you develop a fever that does not go away or gets higher, call your
84 healthcare provider right away. Your healthcare provider will need to examine you to rule
85 out your having a serious infection.

86 **Eye problems:**

87 Changes in vision such as a decrease or loss of vision (blindness) may happen in some
88 patients. You should have an eye exam before you take PEGASYS. If you have eye
89 problems or have had them in the past you may need eye exams while you are taking
90 PEGASYS. Tell your healthcare provider or eye doctor right away if you have changes in
91 your vision while taking PEGASYS.

92 **Body organ problems:**

93 PEGASYS may cause lung problems including: trouble breathing, pneumonia,
94 inflammation of lung tissue, and new or worse high blood pressure in the lungs
95 (pulmonary hypertension), which can be severe and may in some cases lead to death.
96 Certain symptoms like severe stomach pain may mean that your internal organs are being
97 damaged. Cases of weakness, loss of coordination and numbness due to stroke have been
98 reported in patients taking PEGASYS/COPEGUS, including patients with few or no
99 reported risk factors for stroke.

100 **Call your healthcare provider immediately if you develop any of these**
101 **conditions:**

- 102 • **You become very depressed, think about suicide or injuring/killing another**
103 **person**
- 104 • **You have severe chest pain**
- 105 • **You have trouble breathing**
- 106 • **You have a change in your vision**
- 107 • **You become pregnant**
- 108 • **You notice unusual bleeding or bruising**
- 109 • **You have psoriasis (a skin disease) and it gets worse while taking PEGASYS**
- 110 • **You have weakness, loss of coordination, numbness or difficulty speaking**
- 111 • **High fever or a fever that does not go away**
- 112 • **You have severe stomach pain or lower back pain**
- 113 • **Bloody diarrhea**
- 114 • **Skin rash can occur in patients taking PEGASYS. In some patients a rash**
115 **can be serious. If you develop a rash with fever, blisters, or sores in your**
116 **mouth, nose or eyes or conjunctivitis (red or inflamed eyes, like “pink eye”),**
117 **stop using PEGASYS and call your doctor right away**

118
119 *For more information on possible side effects with PEGASYS therapy, alone or in*
120 *combination with COPEGUS, please read the section on “**What are the possible side***
121 ***effects of PEGASYS, and PEGASYS taken with COPEGUS?” in this Medication***
122 *Guide. You should also read the Medication Guide for COPEGUS tablets if you are*
123 *taking that medicine with PEGASYS.*

124 **What is PEGASYS?**

125 PEGASYS is a drug used to treat adults who have a lasting (chronic) infection with
126 hepatitis C virus or hepatitis B virus and who show signs that the virus is damaging the
127 liver. Patients with hepatitis have the virus in their blood and in their liver. PEGASYS
128 reduces the amount of hepatitis C virus in the body and helps the body's immune system
129 fight the virus. The drug COPEGUS are tablets that may be taken with PEGASYS to help
130 fight the virus infection. Do not take COPEGUS by itself.

131 In some patients that have received PEGASYS treatment for approximately one year to
132 treat hepatitis C, the amount of the hepatitis virus in the body was decreased to a level so
133 low that it could not be measured by blood tests. After 3 months of therapy, your
134 healthcare provider may ask you to have a blood test to help determine how you are
135 responding to your treatment.

136 It is not known if PEGASYS, used alone or in combination with COPEGUS, can cure
137 hepatitis (permanently eliminate the virus) or if it can prevent liver failure or liver cancer
138 that is caused by hepatitis infection.

139 It is also not known if PEGASYS, alone or in combination with COPEGUS, will prevent
140 one infected person from infecting another person with hepatitis.

141 **Who should not take PEGASYS, or PEGASYS with COPEGUS?**

142 Do not take PEGASYS or PEGASYS/COPEGUS therapy if you:

- 143 • are pregnant, planning to get pregnant during treatment or during the 6 months after
144 treatment or breast-feeding
- 145 • are a male patient with a female sexual partner who is pregnant or plans to become
146 pregnant at any time while you are being treated with COPEGUS or during the 6
147 months after your treatment has ended
- 148 • have hepatitis caused by your immune system attacking your liver (autoimmune
149 hepatitis)
- 150 • have unstable or severe liver disease
- 151 • had an allergic reaction to another alpha interferon or are allergic to any of the
152 ingredients in PEGASYS or COPEGUS tablets
- 153 • Do not take PEGASYS, alone or in combination with COPEGUS, if you have
154 abnormal red blood cells such as sickle-cell anemia or thalassemia major.
155

156 **If you have ever had any of the following conditions or serious medical**
157 **problems, tell your healthcare provider before you start taking PEGASYS:**

- 158 • History of or current severe mental illness (such as depression or anxiety)
- 159 • History of drug or alcohol addiction or abuse
- 160 • History of heart disease or previous heart attack
- 161 • History of cancer
- 162 • Autoimmune disease (where the body's immune system attacks the body's own
163 cells), such as psoriasis (a skin disease), systemic lupus erythematosus, rheumatoid
164 arthritis
- 165 • Kidney problems

- 166 • Blood disorders (bleeding problems)
- 167 • Diabetes (high blood sugar)
- 168 • Problems with the thyroid gland
- 169 • Liver problems, other than hepatitis C or hepatitis B
- 170 • Colitis (an inflammation of the bowels)
- 171 • Eye problems
- 172 • Sleep problems
- 173 • HIV infection
- 174 • Organ transplant and are taking medicine that keeps your body from rejecting your
- 175 transplant (suppresses your immune system)
- 176

177 **Tell your healthcare provider about all the medicines you take**, including prescription
178 and non-prescription medicines, vitamins and herbal supplements. PEGASYS and certain
179 other medicines may affect each other causing side effects.

180 Especially tell your healthcare provider if you take:

- 181 • the anti-hepatitis B medicine telbivudine (Tyzeka). See “What are the possible side
182 effects of PEGASYS?”.
- 183 • Theophylline: Your healthcare provider may need to monitor the amount of
184 theophylline in your body and make changes to your theophylline dose.
- 185 • HIV medications called nucleoside reverse transcriptase inhibitors (abacavir,
186 didanosine, emtricitabine, lamivudine, tenofovir, stavudine or zidovudine). Some
187 patients developed serious liver problems including death.
- 188 • Didanosine: Do not take COPEGUS and didanosine.
- 189

190 If you have any questions about your health condition or about taking PEGASYS alone
191 or in combination with COPEGUS, you should talk to your healthcare provider.

192 **How should I take PEGASYS, or PEGASYS with COPEGUS?**

193 PEGASYS is given by injection under the skin (subcutaneous injection). PEGASYS
194 comes in two different forms (a liquid in a single use vial and a liquid in a prefilled
195 syringe). Your healthcare provider will determine which is best for you. Your healthcare
196 provider will also decide whether you will take PEGASYS alone or with COPEGUS.
197 Your dose of PEGASYS is given as a single injection once per week. At some point, your
198 healthcare provider may change your dose of PEGASYS or COPEGUS. Do not change
199 your dose unless your healthcare provider tells you to change it. It is important that you
200 take PEGASYS and COPEGUS exactly as your healthcare provider tells you. Once you
201 start treatment with PEGASYS, do not switch to another brand of interferon without
202 talking to your healthcare provider. Other interferons may not have the same effect on the
203 treatment of your disease. Switching brands will also require a change in your dose.

204 Take your prescribed dose of PEGASYS once a week, on the same day of each week and
205 at approximately the same time. Your total dose of COPEGUS tablets should be divided
206 so you take it twice a day with food (breakfast and dinner). Taking half your dose of
207 COPEGUS in the morning and the other half at night will keep the medicine in your body
208 at a steady level. Do not take more than your prescribed dose of PEGASYS or

209 **COPEGUS. Be sure to read the Medication Guide for COPEGUS (ribavirin, USP)**
210 **for complete instructions on how to take the COPEGUS tablets.**

211 Your healthcare provider will train you and/or the person that will be giving you the
212 PEGASYS injections on the proper way to give injections. Whether you give yourself the
213 injection or another person gives the injection to you, it is important that you are
214 comfortable with preparing and injecting a dose of PEGASYS, and you understand the
215 instructions in “How do I inject PEGASYS?” **At the end of this guide there are**
216 **detailed instructions on how to prepare and give yourself an injection of PEGASYS**
217 **using the form your healthcare provider has prescribed for you.**

218 If you miss a dose and you remember **within 2 days** of when you should have taken
219 PEGASYS, give yourself an injection of PEGASYS as soon as you remember. Take your
220 next dose on the day you would usually take it. If **more than 2 days** have passed, ask
221 your healthcare provider what you should do. If you miss a dose of COPEGUS, take the
222 missed dose as soon as you remember during the same day. Do not take 2 doses too close
223 together in time. If it is late in the day, wait until the next day and go back on schedule.
224 **Do not double the next dose.**

225 If you take more than the prescribed amount of PEGASYS, call your healthcare provider
226 right away. Your healthcare provider may want to examine you and take blood for
227 testing.

228 You must get regular blood tests to help your healthcare provider check how the
229 treatment is working and to check for side effects.

230 **What should I avoid while taking PEGASYS, or PEGASYS with COPEGUS?**

- 231 • If you are pregnant do not start taking or continue taking COPEGUS in combination
232 with PEGASYS. (See “**What is the most important information I should know**
233 **about PEGASYS therapy? Problems with Pregnancy**”.)
- 234 • Avoid becoming pregnant while taking PEGASYS, alone or in combination with
235 COPEGUS. PEGASYS, alone or in combination with COPEGUS, may harm your
236 unborn child (death or serious birth defects) or cause you to lose your baby
237 (miscarry). (See “**What is the most important information I should know about**
238 **PEGASYS therapy? Problems with Pregnancy**”.)
- 239 • Do not breast-feed your baby while on PEGASYS, alone or in combination with
240 COPEGUS.
- 241 • **Drinking alcohol**, including beer, wine and liquor. This may make your liver disease
242 worse.
- 243 • **Taking other medicines.** Take only medicines prescribed or approved by your
244 healthcare provider. These include prescription and nonprescription medicines and
245 herbal supplements.

246 **What are the possible side effects of PEGASYS, and PEGASYS taken with** 247 **COPEGUS?**

248 *Also see “What is the most important information I should know about PEGASYS*
249 *therapy?” in this Medication Guide.*

250 PEGASYS and PEGASYS/COPEGUS combination therapy can cause serious side
251 effects including:

- 252 • See “What is the most important information I should know about PEGASYS?”.
- 253 • **Blood problems including anemia:** Anemia is a reduction in the number of red
254 blood cells you have, which can be dangerous, especially if you have heart or
255 breathing problems. Tell your healthcare provider right away if you feel tired, have
256 chest pain or shortness of breath. These may be signs of low red blood cell counts.
- 257 • **Serious infections.**
- 258 • **Stroke:** Some patients may experience weakness, loss of coordination, and numbness
259 due to stroke.
- 260 • **Autoimmune problems:** Some patients may develop a disease where the body’s own
261 immune system begins to attack itself (autoimmune disease) while on PEGASYS
262 therapy. These diseases can include rheumatoid arthritis, systemic lupus
263 erythematosus, psoriasis or thyroid problems. In some patients who already have an
264 autoimmune disease, the disease may worsen while on PEGASYS therapy.
- 265 • **Heart problems:** PEGASYS may cause some patients to experience chest pain, and
266 very rarely a heart attack. Patients who already have heart disease could be at greatest
267 risk. Tell your healthcare provider if you have or have had a heart problem in the past.
- 268 • **Liver problems:** Some patients may develop worsening of liver function. Some of
269 the symptoms may include stomach bloating, confusion, brown urine, and yellow
270 eyes. Tell your healthcare provider immediately if any of these symptoms occur.
- 271 • **Nerve problems:** People who take PEGASYS or other alpha interferon products with
272 telbivudine (Tyzeka) can have nerve problems such as continuing numbness, tingling,
273 or burning sensation in the arms or legs (peripheral neuropathy). Call your healthcare
274 provider if you have any of these symptoms.
- 275 • **Harm to unborn children:** PEGASYS and PEGASYS/COPEGUS may cause birth
276 defects or death of an unborn child. For more details, *see “What is the most important
277 information I should know about PEGASYS therapy?” in this Medication Guide.*
278

279 Common, but less serious, side effects include:

- 280 • **Flu-like symptoms:** Most patients who take PEGASYS have flu-like symptoms that
281 usually lessen after the first few weeks of treatment. Flu-like symptoms may include
282 fever, chills, muscle aches, joint pain, and headaches. Taking pain and fever reducers
283 such as acetaminophen or ibuprofen before you take PEGASYS can help with these
284 symptoms. You can also try taking PEGASYS at night. You may be able to sleep
285 through the symptoms.
- 286 • **Extreme fatigue (tiredness):** Many patients may become extremely tired while on
287 PEGASYS therapy.
- 288 • **Upset stomach:** Nausea, taste changes, diarrhea, and loss of appetite occur
289 commonly.
- 290 • **Blood sugar problems:** Some patients may develop a problem with the way their
291 body controls their blood sugar and may develop diabetes.

- 292 • **Thyroid problems:** Some patients develop changes in the function of their thyroid.
293 Symptoms of thyroid changes include the inability to concentrate, feeling cold or hot
294 all the time, a change in your weight, and changes to your skin.
- 295 • **Skin reactions:** Some patients may develop redness, swelling, dry or itchy skin at the
296 site of injection. If after several days these symptoms do not disappear, contact your
297 healthcare provider. You may get a rash during therapy. If this occurs, your
298 healthcare provider may recommend medicine to treat the rash.
- 299 • **Hair thinning:** Temporary hair loss is not uncommon during treatment with
300 PEGASYS.
- 301 • **Trouble sleeping**

302 These are not all of the side effects of PEGASYS, and PEGASYS taken with COPEGUS.
303 Your healthcare provider or pharmacist can give you a more complete list. Call your
304 doctor for medical advice about side effects. You may report side effects to FDA at 1-
305 800-FDA-1088. You may also report side effects to Genentech at 1-888-835-2555.

306 Talk to your healthcare provider if you are worried about side effects or find them very
307 bothersome.

308 **General advice about prescription medicines**

309 Medicines are sometimes prescribed for purposes other than those listed in a Medication
310 Guide. If you have any concerns or questions about PEGASYS, contact your healthcare
311 provider. Do not use PEGASYS for a condition or person other than that for which it is
312 prescribed. If you want to know more about PEGASYS, your healthcare provider or
313 pharmacist will be able to provide you with detailed information that is written for
314 healthcare providers.

315 If you are taking COPEGUS (ribavirin, USP) in combination with PEGASYS, also read
316 the Medication Guide supplied with that medicine.

317 Keep this and all drugs out of the reach of children.

318 This Medication Guide has been approved by the US Food and Drug Administration.

319 MG Revised: January 2010

320 **Medication Guide Appendix: Instructions for Preparing and Giving a Dose with a**
321 **PEGASYS Prefilled Syringe**

322 **How should I store PEGASYS Prefilled Syringes?**

323 PEGASYS must be stored in the refrigerator at a temperature of 2°C to 8°C (36°F to
324 46°F). Do not leave PEGASYS outside of the refrigerator for more than 24 hours. Do not
325 freeze PEGASYS. Keeping PEGASYS at temperatures outside the recommended range
326 can destroy the medicine.

327 Each PEGASYS prefilled syringe can only be used once. Discard after use.

328 To avoid product foaming, do not shake the prefilled syringe of PEGASYS.

329 Protect PEGASYS from light during storage.

330 Keep this and all other medicines out of the reach of children.

331 **How do I prepare and inject PEGASYS?**

332 You should read through all of these directions and ask your healthcare provider for help
333 if you have any questions before trying to give yourself an injection. It is important to
334 follow these directions carefully. Talk to your healthcare provider if you have any
335 questions about PEGASYS.

336 Your healthcare provider may not want you to take all the medicine that comes in the
337 prefilled syringe. To appropriately administer the dose that your healthcare provider tells
338 you to take, you may have to get rid of some of the medicine before injecting the
339 medicine.

340 If you ever switch between using prefilled syringes and vials, talk to your healthcare
341 provider about how much PEGASYS to use. Equal volumes of liquid from the prefilled
342 syringes and the vials DO NOT contain the same amount of PEGASYS. If you switch
343 between prefilled syringes and vials, you will have to adjust the volume of liquid that you
344 use to give your injection. If you do not adjust this, you could accidentally take too much
345 or too little of your medicine.

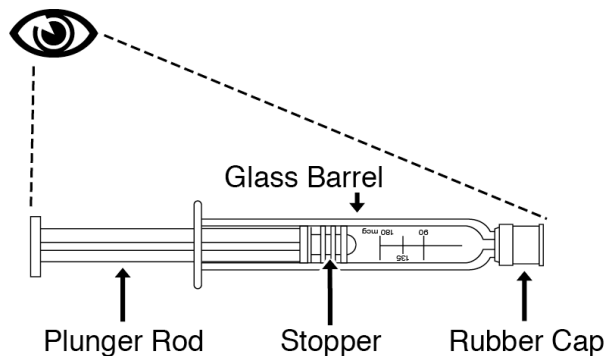
346 If you are giving this injection to someone else, a healthcare provider must teach you how
347 to avoid needle sticks. Being stuck by a used needle can pass diseases on to you.

348 The prefilled syringes are used for injecting PEGASYS under the surface of the skin
349 (subcutaneous).

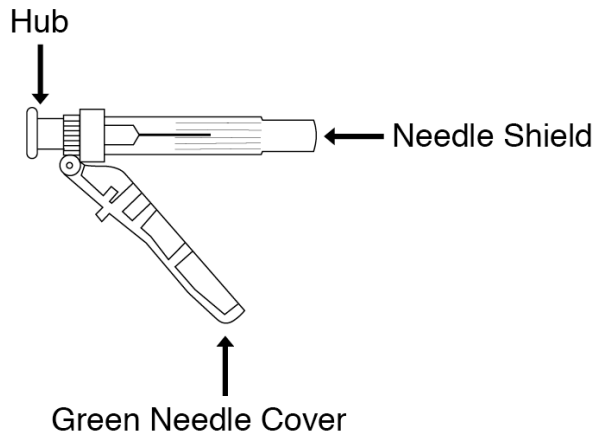
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- 352 1. Collect all the materials you will need before you start to give the injection:
 - 353 • One PEGASYS prefilled syringe Monthly Convenience Pack containing an
354 inner carton holding the PEGASYS prefilled syringe
 - 355 • A puncture-resistant container for cleaning up when you are finished
356
- 357 2. Open the convenience pack and look at the contents.
 - 358 • Each convenience pack has everything you need for the PEGASYS injection.

- 359 – 4 single use syringes filled with medicine (should be colorless to light
360 yellow)
- 361 – four 27-gauge, ½-inch needles with needle-stick protection device
- 362 – 4 alcohol swabs
- 363 3. Take the syringe out of the refrigerator. If there is foam in the solution, put it back in
364 the refrigerator for use at a later time and use another syringe.
- 365 4. Lay the syringe on a flat clean surface and wait a few minutes until it reaches room
366 temperature. If you notice condensation water on the outside of the syringe, wait
367 another few minutes until it disappears.
- 368 5. Wash your hands with soap and warm water to prevent infection.
- 369 6. After the syringe has warmed up, pick it up by the glass barrel and look at it carefully.
- 370 • Do not use PEGASYS if:
371 – the medicine is cloudy
372 – the medicine has particles floating in it
373 – the medicine is any color besides colorless to light yellow
374 – the expiration date has passed

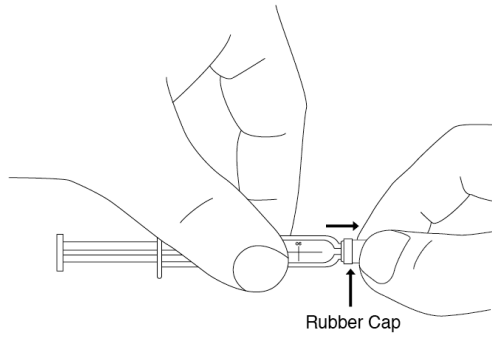


- 375
- 376 7. Attachment of the needle to the PEGASYS prefilled syringe:
377 • Remove the needle from its package. Do not remove the needle shield yet.
378 Keep the needle covered until just before you give the injection.



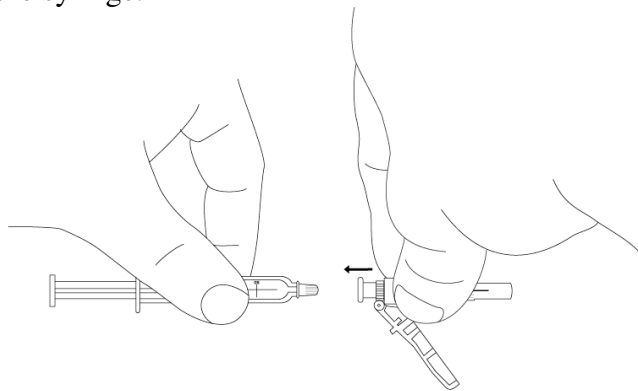
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- Remove and discard the rubber cap from the tip of the syringe barrel.



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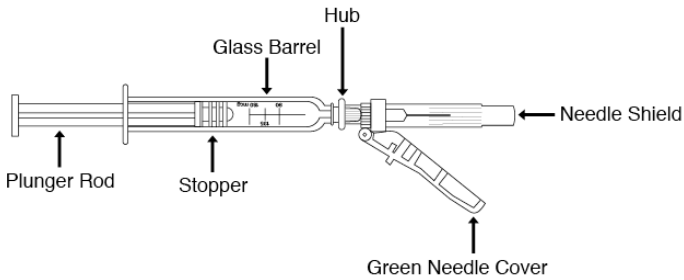
- Hold the needle close to the hub where the green needle cover connects.
- Put the needle onto the syringe by using an easy twisting motion to tighten the needle onto the syringe.



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- Here is a picture of the assembled syringe:



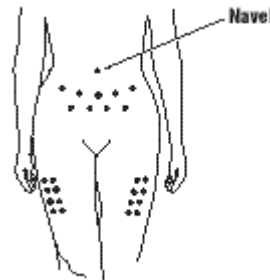
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- Keep the syringe in a horizontal position until ready for use.
- If you need to set the syringe down, make sure the plastic needle shield covers the needle. Never let the needle touch any surface.

395 8. Decide where you will give the injection.

- Pick a place on your stomach or thigh (see the picture below). Avoid your navel and waistline. You should use a different place each time you give yourself an injection.

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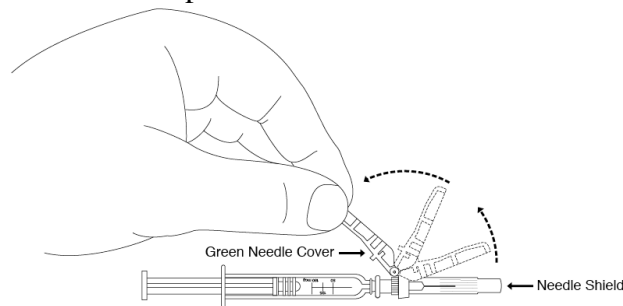
401 9. Prepare your skin for the injection.

- To minimize the discomfort from injections, you may want to gently tap the area where you plan to give yourself an injection.
- Clean the area using the alcohol pad. Let the skin dry for 10 seconds.

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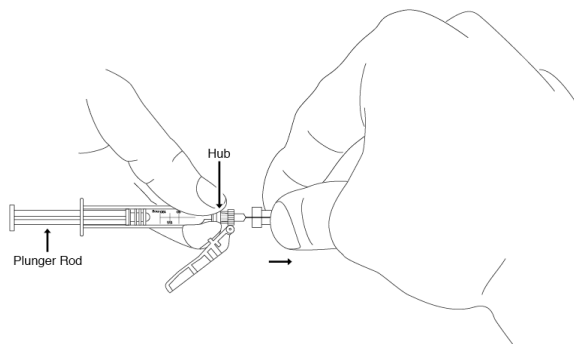
405 10. Prepare the syringe for injection.

- 406
- 407 • Pull the green needle cover back from the needle toward the syringe barrel.
 - 408 The green needle cover will remain in the position you set, do not remove it.



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- Hold the syringe-needle assembly tightly at the hub.



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- Remove the clear plastic needle shield covering the needle by pulling it straight off.

417 11. Remove air bubbles from the syringe.

- 418
- 419 • Hold the syringe with the needle pointing up to the ceiling.
 - 420 • If you see little bubbles, pull down slightly on the plunger rod.
 - 421 • Using your thumb and finger, gently tap the syringe to bring air bubbles to the top (small air bubbles may remain on the glass surface).
 - 422 • Press the plunger in slightly to push air bubbles out of the syringe.
 - 423 • If you find that there is still small air bubbles on glass surface after you push
 - 424 the air bubbles out, you can still give yourself the injection, the small air
 - 425 bubbles will not hurt you.

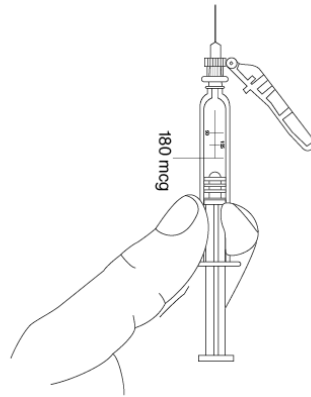
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12. Dose adjustment.

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- 429 • Your healthcare provider may not want you to take all the medicine that comes
 - 430 in the prefilled syringe.
 - 431 • To appropriately administer the dose that your healthcare provider tells you to
 - 432 take, you may have to get rid of some of the medicine before injecting the

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- The syringe has markings for 180 mcg, 135 mcg, and 90 mcg. Your healthcare provider will tell you which mark to use.



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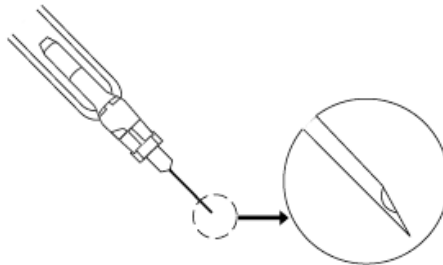
- Once you know which mark to use, slowly and carefully press on the plunger rod of the syringe to push out medicine from the syringe. Keep pressing until the edge of the plunger stopper reaches the right mark on the side of the syringe.
- Do not decrease or increase your dose of PEGASYS unless your healthcare provider tells you to.

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445 13. Give the injection of PEGASYS.

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- Position the point of the needle (the bevel) so it is facing up.



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- Pinch a fold of skin on your stomach or thigh firmly with your thumb and forefinger.



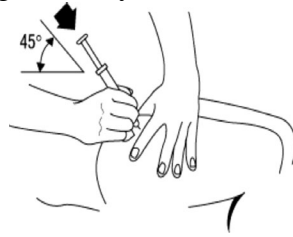
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- Hold the syringe like a pencil at a 45° to 90° angle to your skin. In one quick motion, insert the needle as far as it will go into the pinched area of skin. Pull the plunger of the syringe back very slightly. If blood comes into the syringe, the needle has entered a blood vessel. **Do not inject. Withdraw the needle and discard the syringe as outlined in step 14. Repeat the above steps with a new prefilled syringe and prepare a new site.**

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- If no blood appears, release your skin and slowly push the plunger all the way down so that you get all of your medicine.



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- Pull out the needle at same angle you put it in.

462

- Wipe the area with an alcohol swab.

463

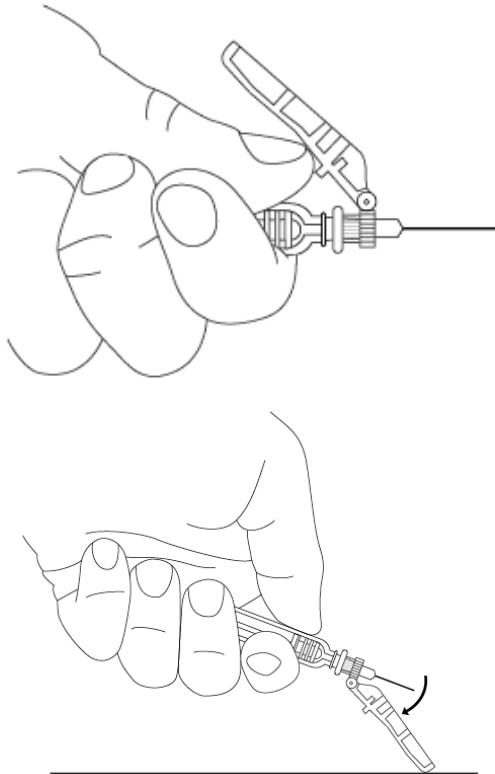
14. For safety reasons, before you dispose of the syringe and needle, push the green needle cover toward the needle. Then place the free end of the green cap on a flat surface and push down on it until it clicks and covers over the needle. Always place used syringes and needles in a puncture-resistant container immediately after use and never reuse them. Keep your disposal container out of the reach of children.

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How should I dispose of materials used to inject PEGASYS?

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There may be special state and local laws for disposal of used needles and syringes. Your healthcare provider or pharmacist should provide you with instructions on how to properly dispose of your used syringes and needles. Always follow these instructions.

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The instructions below should be used as a general guide for proper disposal:

475

- The needles and syringes should never be reused.

- 476 • Place all used needles and syringes in a puncture-proof disposable container that is
477 available through your pharmacy or healthcare provider (Sharp’s container).
478 • DO NOT use glass or clear plastic containers for disposal of needles and syringes.
479 • Dispose of the full container as instructed by your healthcare provider or pharmacist.
480

481 **DO NOT throw the container in your household trash. DO NOT recycle. Keep the**
482 **container out of the reach of children.**

483 MG Appendix: Prefilled Syringe revision date: April 2009

484 **Medication Guide Appendix: Instructions for Preparing and Giving a Dose with a**
485 **PEGASYS Vial**

486 **How should I store PEGASYS vials?**

487 PEGASYS must be stored in the refrigerator at a temperature of 2°C to 8°C (36°F to
488 46°F). Do not leave PEGASYS outside of the refrigerator for more than 24 hours. Do not
489 freeze PEGASYS. Keeping PEGASYS at temperatures outside the recommended range
490 can destroy the medicine.

491 Each PEGASYS vial can only be used once. Discard after use.

492 Do not shake the vial of PEGASYS. If PEGASYS is shaken too hard, it will not work
493 properly.

494 Protect PEGASYS from light during storage.

495 Keep this and all other medicines out of the reach of children.

496 **How do I inject PEGASYS?**

497 The following instructions will help you learn how to measure your dose and give
498 yourself an injection of PEGASYS. You should read through all of these directions and
499 ask your healthcare provider for help if you have any questions before trying to give
500 yourself an injection. It is important to follow these directions carefully. Talk to your
501 healthcare provider if you have any questions about PEGASYS.

502 If you are giving an injection to someone else, a healthcare provider must teach you how
503 to avoid needle sticks. Being stuck by a used needle can pass diseases on to you.

- 504 1. Collect all the materials you will need before you start to give the injection:
- 505 • One vial of PEGASYS
 - 506 • One syringe and needle
 - 507 • Several alcohol pads
 - 508 • A puncture-resistant container to dispose of the needle and syringe when you are
509 finished
- 510 2. Check the date on the carton the PEGASYS comes in and make sure the expiration
511 date has not passed, then remove a vial from the package and look at the medicine.
- 512 • Do not use PEGASYS if:
 - 513 – the medicine is cloudy

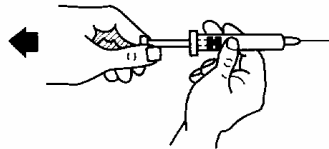
- 514 – the medicine has particles floating in it
515 – the medicine is any color besides colorless to light yellow
516 – the expiration date has passed
- 517 3. Warm the refrigerated medicine by gently rolling it in the palms of your hands for
518 about one minute. Do not shake.
519 4. Wash your hands with soap and warm water to prevent infection.
520 5. Take the vial of PEGASYS and flip off the plastic top covering the vial opening, and
521 clean the rubber stopper on the top of the vial with a different alcohol pad.



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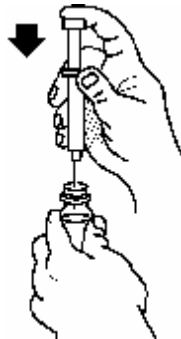
523 **If you are not sure how much medicine to use or which mark to use, STOP and call**
524 **your healthcare provider right away.**

- 525 6. Remove the needle and syringe from their packaging and attach the needle to the end
526 of the syringe.
527 • Pull the plunger back so the end of it is to the mark on the syringe barrel that
528 matches the dose prescribed for you by your healthcare provider. This will pull air
529 into the syringe barrel.



530

- 531 • Push the needle through the center of the stopper on the vial.
532 • Slowly inject all the air from the syringe into the air space above the solution. Do
533 not inject air into the fluid.



534

- 535 • Keep the needle inside the vial and turn both upside down. Hold the vial and
536 syringe straight up. Slowly pull back on the plunger until the medicine is in the
537 syringe up to the mark that matches your dose. Make sure the needle tip always
538 stays in the medicine (not in the air space above it).



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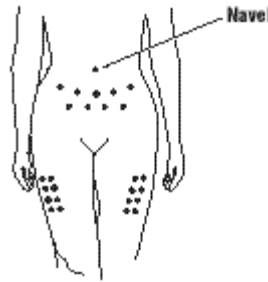
- 540 • When the medicine is up to the right mark on the syringe barrel, take the syringe
541 and needle out of the rubber stopper on the vial.
- 542 • Keep the syringe pointing up until you are ready to use it.
- 543 • If you need to set the syringe down, make sure that you never let the needle touch
544 any surface.

545 7. Remove air bubbles from the syringe.

- 546 • Hold the syringe with the needle pointing up to the ceiling.
- 547 • Using your thumb and finger, tap the syringe to bring air bubbles to the top.
- 548 • Press the plunger in slightly to push air bubbles out of the syringe.

549 8. Decide where you will give the injection.

- 550 • Pick a place on your stomach or thigh (see the picture below). Avoid your navel
551 and waistline. You should use a different place each time you give yourself an
552 injection.



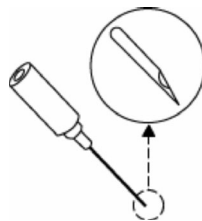
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554 9. Prepare your skin for the injection.

- 555 • To minimize the discomfort from injections, you may want to gently tap the area
556 where you plan to give yourself an injection.
- 557 • Clean the area using an alcohol pad. Let the skin dry for 10 seconds.
- 558

559 10. Give the injection of PEGASYS.

- 560 • Position the point of the needle (the bevel) so it is facing up.
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- 563 • Pinch a fold of skin on your stomach or thigh firmly between your thumb and
564 forefinger.

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- Hold the syringe like a pencil at a 45° to 90° angle to your skin. In one quick motion, insert the needle as far as it will go into the pinched area of skin. Pull the plunger of the syringe back very slightly. If blood comes into the syringe, the needle has entered a blood vessel. **Do not inject. Withdraw the needle and discard the syringe as outlined in step 11. Repeat the above steps with a new vial and syringe and prepare a new site.**
 - If no blood appears, release your skin and slowly push the plunger all the way down so that you get all of your medicine.



576

- 577
- Pull out the needle at same angle you put it in. Wipe the area with an alcohol pad.
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- 582
11. For safety reasons, always place used syringes and needles in a puncture-resistant container immediately after use and never reuse them.
- If you are using a syringe with a needle-stick protection device, before you dispose of the syringe and needle, place the free end of the green cap on a flat surface and push down on it until it clicks and covers over the needle.

583 **How should I dispose of materials used to inject PEGASYS?**

584 There may be special state and local laws for disposal of used needles and syringes. Your
585 healthcare provider or pharmacist should provide you with instructions on how to
586 properly dispose of your used syringes and needles. Always follow these instructions.

587 The instructions below should be used as a general guide for proper disposal:

- 588
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- 593
- The needles and syringes should never be reused.
 - Place all used needles and syringes in a puncture-proof disposable container that is available through your pharmacy or healthcare provider (Sharp's container).
 - DO NOT use glass or clear plastic containers for disposal of needles and syringes.
 - Dispose of the full container as instructed by your healthcare provider or pharmacist.

594 **DO NOT throw the container in your household trash. DO NOT recycle. Keep the**
595 **container out of the reach of children.**

596 MG Appendix: Vial revision date: October 2008
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598
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602 Nutley, NJ 07110-1199
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A Member of the Roche Group
1 DNA Way
South San Francisco, CA 94080-4990
604
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