

PEGASYS® (peginterferon alfa-2a)

1008 **Storage**

1009 Store in the refrigerator at 2°C to 8°C (36°F to 46°F). Do not freeze or shake. Protect
1010 from light. Vials and prefilled syringes are for single use only. Discard any unused
1011 portion.

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1013 Corporation.

1014 Revised: June 2008

1015 **MEDICATION GUIDE**

1016 **PEGASYS®**

1017 **(peginterferon alfa-2a)**

1018 Before you start taking PEGASYS (PEG-ah-sis), alone or in combination with
1019 COPEGUS® (Co-PEG-UHS), please read this Medication Guide carefully. Read this
1020 Medication Guide each time you refill your prescription in case new information has
1021 been added and make sure the pharmacist has given you the medicine your healthcare
1022 provider prescribed for you. Reading the information in this Medication Guide does not
1023 take the place of talking with your healthcare provider.

1024 *If you are taking PEGASYS in combination with COPEGUS, you should also read the*
1025 *Medication Guide for COPEGUS (ribavirin, USP) Tablets.*

1026 **What is the most important information I should know about PEGASYS**
1027 **therapy?**

1028 PEGASYS, taken alone or in combination with COPEGUS, is a treatment for some
1029 people who are infected with hepatitis C virus. PEGASYS taken alone is a treatment for
1030 some people who are infected with the hepatitis B virus. However, PEGASYS and
1031 COPEGUS can have serious side effects that may cause death in rare cases. Before
1032 starting PEGASYS therapy, you should talk with your healthcare provider about the
1033 possible benefits and the possible side effects of treatment, to decide if either of these
1034 treatments is right for you. If you begin treatment you will need to see your healthcare
1035 provider regularly for examinations and blood tests to make sure your treatment is
1036 working and to check for side effects.

1037 The most serious possible side effects of PEGASYS taken alone or in combination with
1038 COPEGUS include:

1039 **Risks to Pregnancy:**

1040 **Taking PEGASYS in combination with COPEGUS tablets can cause death, serious**
1041 **birth defects or other harm to your unborn child. Therefore, if you are pregnant or**
1042 **your partner is pregnant or plans to become pregnant, do not take**
1043 **PEGASYS/COPEGUS combination therapy. Female patients and female partners**
1044 **of male patients being treated with PEGASYS/COPEGUS combination therapy**
1045 **must not become pregnant during treatment and for 6 months after treatment has**
1046 **stopped. During this time, you must have pregnancy tests that show you are not**

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1047 **pregnant. You must also use two effective forms of birth control during therapy and**
1048 **for 6 months after stopping therapy. Male patients should use a condom with**
1049 **spermicide as one of the two forms.** You must use birth control even if you believe that
1050 you are not fertile or that your fertility is low. You should talk to your healthcare provider
1051 about birth control for you and your partner.

1052 **If you are pregnant, you or your male partner must not take PEGASYS/COPEGUS**
1053 **combination therapy. If you or your partner are being treated and you become**
1054 **pregnant either during treatment or within 6 months of stopping treatment, call**
1055 **your healthcare provider right away.**

1056 If you or a female sexual partner becomes pregnant, you should tell your healthcare
1057 provider. There is a Ribavirin Pregnancy Registry that collects information about
1058 pregnancy outcomes of female patients and female partners of male patients exposed to
1059 ribavirin. You or your healthcare provider are encouraged to contact the Registry at 1-
1060 800-593-2214.

1061 **Mental health problems:**

1062 PEGASYS may cause some patients to develop mood or behavioral problems. Signs of
1063 these problems include irritability (getting easily upset), depression (feeling low, feeling
1064 bad about yourself or feeling hopeless), and anxiety. Some patients may have aggressive
1065 behavior. Some patients may develop thoughts about ending their lives (suicidal
1066 thoughts) and may attempt to do so. A few patients have even ended their lives. Former
1067 drug addicts may fall back into drug addiction or overdose. You must tell your healthcare
1068 provider if you are being treated for a mental illness or have a history of mental illness or
1069 if you are or have ever been addicted to drugs or alcohol. Call your healthcare provider
1070 immediately if you develop any of these problems while on PEGASYS treatment.

1071 **Blood problems:**

1072 Many patients taking PEGASYS have had a drop in the number of their white blood cells
1073 and their platelets. If the numbers of these blood cells are too low, you could be at risk for
1074 serious infections or bleeding.

1075 COPEGUS causes a decrease in the number of your red blood cells (anemia). This can be
1076 dangerous, especially for patients who already have heart or circulatory (cardiovascular)
1077 problems. If you have or have ever had any cardiovascular problems, talk with your
1078 healthcare provider before taking the combination of PEGASYS and COPEGUS.

1079 **Liver problems:**

1080 Infrequently, some patients with hepatitis C and liver scarring can develop sudden severe
1081 worsening (failure) of their liver disease while taking PEGASYS. Patients infected with
1082 both the hepatitis C virus and HIV can have an increased chance of having liver failure
1083 during PEGASYS treatment.

1084 Some patients taking PEGASYS for hepatitis B have had a rise in a blood test that
1085 measures liver inflammation. If you have a rise in this blood test, your liver may need to
1086 be watched more closely with additional blood tests.

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1087 **Infections:**

1088 Some patients taking interferon have had serious infections. Sometimes these infections
1089 have been fatal. If you develop a fever that does not go away or gets higher, call your
1090 healthcare provider right away. Your healthcare provider will need to examine you to rule
1091 out your having a serious infection.

1092 **Body organ problems:**

1093 Some patients may experience lung problems (such as difficulty breathing or pneumonia)
1094 and eye problems that can cause blurred vision or loss of your vision. Cases of weakness,
1095 loss of coordination and numbness due to stroke have been reported in patients taking
1096 PEGASYS, including patients with few or no expected risk factors for stroke.

1097 **Call your healthcare provider immediately if you develop any of these** 1098 **conditions:**

- 1099 • **You become very depressed, think about suicide or injuring/killing another**
1100 **person**
- 1101 • **You have severe chest pain**
- 1102 • **You have trouble breathing**
- 1103 • **You have a change in your vision**
- 1104 • **You become pregnant**
- 1105 • **You notice unusual bleeding or bruising**
- 1106 • **You have psoriasis (a skin disease) and it gets worse while taking PEGASYS**
- 1107 • **High fever or a fever that does not go away**
- 1108 • **You have severe stomach pain or lower back pain**
- 1109 • **Bloody diarrhea**
- 1110 • **Skin rash can occur in patients taking PEGASYS. In some patients a rash**
1111 **can be serious. If you develop a rash with fever, blisters, or sores in your**
1112 **mouth, nose or eyes or conjunctivitis (red or inflamed eyes, like “pink eye”),**
1113 **stop using PEGASYS and call your doctor right away**

1114

1115 *For more information on possible side effects with PEGASYS therapy, alone or in*
1116 *combination with COPEGUS, please read the section on “What are the possible side*
1117 *effects of PEGASYS, and PEGASYS taken with COPEGUS?” in this Medication*
1118 *Guide. You should also read the Medication Guide for COPEGUS tablets if you are*
1119 *taking that medicine with PEGASYS.*

1120 **What is PEGASYS?**

1121 PEGASYS is a drug used to treat adults who have a lasting (chronic) infection with
1122 hepatitis C virus or hepatitis B virus and who show signs that the virus is damaging the
1123 liver. Patients with hepatitis have the virus in their blood and in their liver. PEGASYS
1124 reduces the amount of hepatitis C virus in the body and helps the body’s immune system
1125 fight the virus. The drug COPEGUS are tablets that may be taken with PEGASYS to help
1126 fight the virus infection. Do not take COPEGUS by itself.

1127 In some patients that have received PEGASYS treatment for approximately one year to
1128 treat hepatitis C, the amount of the hepatitis virus in the body was decreased to a level so

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1129 low that it could not be measured by blood tests. After 3 months of therapy, your
1130 healthcare provider may ask you to have a blood test to help determine how you are
1131 responding to your treatment.

1132 It is not known if PEGASYS, used alone or in combination with COPEGUS, can cure
1133 hepatitis (permanently eliminate the virus) or if it can prevent liver failure or liver cancer
1134 that is caused by hepatitis infection.

1135 It is also not known if PEGASYS, alone or in combination with COPEGUS, will prevent
1136 one infected person from infecting another person with hepatitis.

1137 Who should not take PEGASYS, or PEGASYS with COPEGUS?

1138 Do not take PEGASYS or PEGASYS/COPEGUS therapy if you:

- 1139 • are pregnant, planning to get pregnant during treatment or during the 6 months after
1140 treatment or breast-feeding
- 1141 • are a male patient with a female sexual partner who is pregnant or plans to become
1142 pregnant at any time while you are being treated with COPEGUS or during the 6
1143 months after your treatment has ended
- 1144 • have hepatitis caused by your immune system attacking your liver (autoimmune
1145 hepatitis)
- 1146 • have unstable or severe liver disease
- 1147 • had an allergic reaction to another alpha interferon or are allergic to any of the
1148 ingredients in PEGASYS or COPEGUS tablets
- 1149 • Do not take PEGASYS, alone or in combination with COPEGUS, if you have
1150 abnormal red blood cells such as sickle-cell anemia or thalassemia major.
1151

**1152 If you have ever had any of the following conditions or serious medical
1153 problems, tell your healthcare provider before you start taking PEGASYS:**

- 1154 • History of or current severe mental illness (such as depression or anxiety)
- 1155 • History of drug or alcohol addiction or abuse
- 1156 • History of heart disease or previous heart attack
- 1157 • History of cancer
- 1158 • Autoimmune disease (where the body's immune system attacks the body's own
1159 cells), such as psoriasis (a skin disease), systemic lupus erythematosus, rheumatoid
1160 arthritis
- 1161 • Kidney problems
- 1162 • Blood disorders
- 1163 • You take a medicine called theophylline
- 1164 • Diabetes (high blood sugar)
- 1165 • Problems with the thyroid gland
- 1166 • Liver problems, other than hepatitis C or hepatitis B
- 1167 • Colitis (an inflammation of the bowels)
1168

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1169 You should tell your healthcare provider if you are taking or planning to take other
1170 prescription or nonprescription medicines or vitamin and mineral supplements or herbal
1171 medicines.

1172 Co-administration of COPEGUS and didanosine is not recommended.

1173 If you have any questions about your health condition or about taking PEGASYS alone
1174 or in combination with COPEGUS, you should talk to your healthcare provider.

1175 How should I take PEGASYS, or PEGASYS with COPEGUS?

1176 PEGASYS is given by injection under the skin (subcutaneous injection). PEGASYS
1177 comes in two different forms (a liquid in a single use vial and a liquid in a prefilled
1178 syringe). Your healthcare provider will determine which is best for you. Your healthcare
1179 provider will also decide whether you will take PEGASYS alone or with COPEGUS.
1180 Your dose of PEGASYS is given as a single injection once per week. At some point, your
1181 healthcare provider may change your dose of PEGASYS or COPEGUS. Do not change
1182 your dose unless your healthcare provider tells you to change it. It is important that you
1183 take PEGASYS and COPEGUS exactly as your healthcare provider tells you. Once you
1184 start treatment with PEGASYS, do not switch to another brand of interferon without
1185 talking to your healthcare provider. Other interferons may not have the same effect on the
1186 treatment of your disease. Switching brands will also require a change in your dose.

1187 Take your prescribed dose of PEGASYS once a week, on the same day of each week and
1188 at approximately the same time. Your total dose of COPEGUS tablets should be divided
1189 so you take it twice a day with food (breakfast and dinner). Taking half your dose of
1190 COPEGUS in the morning and the other half at night will keep the medicine in your body
1191 at a steady level. Do not take more than your prescribed dose of PEGASYS or
1192 COPEGUS. **Be sure to read the Medication Guide for COPEGUS (ribavirin, USP)**
1193 **for complete instructions on how to take the COPEGUS tablets.**

1194 Your healthcare provider will train you and/or the person that will be giving you the
1195 PEGASYS injections on the proper way to give injections. Whether you give yourself the
1196 injection or another person gives the injection to you, it is important that you are
1197 comfortable with preparing and injecting a dose of PEGASYS, and you understand the
1198 instructions in "How do I inject PEGASYS?" **At the end of this guide there are**
1199 **detailed instructions on how to prepare and give yourself an injection of PEGASYS**
1200 **using the form your healthcare provider has prescribed for you.**

1201 If you miss a dose and you remember **within 2 days** of when you should have taken
1202 PEGASYS, give yourself an injection of PEGASYS as soon as you remember. Take your
1203 next dose on the day you would usually take it. If **more than 2 days** have passed, ask
1204 your healthcare provider what you should do. If you miss a dose of COPEGUS, take the
1205 missed dose as soon as you remember during the same day. Do not take 2 doses too close
1206 together in time. If it is late in the day, wait until the next day and go back on schedule.
1207 **Do not double the next dose.**

1208 If you take more than the prescribed amount of PEGASYS, call your healthcare provider
1209 right away. Your healthcare provider may want to examine you and take blood for
1210 testing.

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1211 You must get regular blood tests to help your healthcare provider check how the
1212 treatment is working and to check for side effects.

1213 **What should I avoid while taking PEGASYS, or PEGASYS with COPEGUS?**

- 1214 • If you are pregnant do not start taking or continue taking COPEGUS in combination
1215 with PEGASYS. (See “**What is the most important information I should know**
1216 **about PEGASYS therapy? Risks to Pregnancy**”.)
- 1217 • Avoid becoming pregnant while taking PEGASYS, alone or in combination with
1218 COPEGUS. PEGASYS, alone or in combination with COPEGUS, may harm your
1219 unborn child (death or serious birth defects) or cause you to lose your baby
1220 (miscarry). (See “**What is the most important information I should know about**
1221 **PEGASYS therapy? Risks to Pregnancy**”.)
- 1222 • Do not breast-feed your baby while on PEGASYS, alone or in combination with
1223 COPEGUS.

1224 **What are the possible side effects of PEGASYS, and PEGASYS taken with** 1225 **COPEGUS?**

1226 Possible, serious side effects include:

- 1227 • **Risk to pregnancy, mental health problems including suicidal thoughts, blood**
1228 **problems, infections, and body organ problems:** See “*What is the most important*
1229 *information I should know about PEGASYS therapy?*” in this Medication Guide.
- 1230 • **Autoimmune problems:** Some patients may develop a disease where the body’s own
1231 immune system begins to attack itself (autoimmune disease) while on PEGASYS
1232 therapy. These diseases can include psoriasis or thyroid problems. In some patients
1233 who already have an autoimmune disease, the disease may worsen while on
1234 PEGASYS therapy.
- 1235 • **Heart problems:** PEGASYS may cause some patients to experience chest pain, and
1236 very rarely a heart attack. Patients who already have heart disease could be at greatest
1237 risk. Tell your healthcare provider if you have or have had a heart problem in the past.
- 1238 • **Liver problems:** Some patients may develop worsening of liver function. Some of
1239 the symptoms may include stomach bloating, confusion, brown urine, and yellow
1240 eyes. Tell your healthcare provider immediately if any of these symptoms occur.

1241
1242 Common, but less serious, side effects include:

- 1243 • **Flu-like symptoms:** Most patients who take PEGASYS have flu-like symptoms that
1244 usually lessen after the first few weeks of treatment. Flu-like symptoms may include
1245 fever, chills, muscle aches, joint pain, and headaches. Taking pain and fever reducers
1246 such as acetaminophen or ibuprofen before you take PEGASYS can help with these
1247 symptoms. You can also try taking PEGASYS at night. You may be able to sleep
1248 through the symptoms.
- 1249 • **Extreme fatigue (tiredness):** Many patients may become extremely tired while on
1250 PEGASYS therapy.
- 1251 • **Upset stomach:** Nausea, taste changes, diarrhea, and loss of appetite occur
1252 commonly.

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- 1253 • **Blood sugar problems:** Some patients may develop a problem with the way their
1254 body controls their blood sugar and may develop diabetes.
- 1255 • **Skin reactions:** Some patients may develop rash, dry or itchy skin, and redness and
1256 swelling at the site of injection.
- 1257 • **Hair thinning:** Temporary hair loss is not uncommon during treatment with
1258 PEGASYS.
- 1259 • **Trouble sleeping**

1260 These are not all of the side effects of PEGASYS, and PEGASYS taken with COPEGUS.
1261 Your healthcare provider or pharmacist can give you a more complete list. Call your
1262 doctor for medical advice about side effects. You may report side effects to FDA at 1-
1263 800-FDA-1088 or Roche at 1-800-526-6367.

1264 Talk to your healthcare provider if you are worried about side effects or find them very
1265 bothersome.

1266 General advice about prescription medicines

1267 Medicines are sometimes prescribed for purposes other than those listed in a Medication
1268 Guide. If you have any concerns or questions about PEGASYS, contact your healthcare
1269 provider. Do not use PEGASYS for a condition or person other than that for which it is
1270 prescribed. If you want to know more about PEGASYS, your healthcare provider or
1271 pharmacist will be able to provide you with detailed information that is written for health-
1272 care providers.

1273 If you are taking COPEGUS (ribavirin, USP) in combination with PEGASYS, also read
1274 the Medication Guide supplied with that medicine.

1275 Keep this and all drugs out of the reach of children.

1276 This Medication Guide has been approved by the US Food and Drug Administration.

1277 MG Revised: October 2008

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1278 **Medication Guide Appendix: Instructions for Preparing and Giving a Dose with a**
1279 **PEGASYS® Prefilled Syringe**

1280 **How should I store PEGASYS Prefilled Syringes?**

1281 PEGASYS must be stored in the refrigerator at a temperature of 2°C to 8°C (36°F to
1282 46°F). Do not leave PEGASYS outside of the refrigerator for more than 24 hours. Do not
1283 freeze PEGASYS. Keeping PEGASYS at temperatures outside the recommended range
1284 can destroy the medicine.

1285 Each PEGASYS prefilled syringe can only be used once. Discard after use.

1286 Do not shake the prefilled syringe of PEGASYS. If PEGASYS is shaken too hard, it will
1287 not work properly.

1288 Protect PEGASYS from light during storage.

1289 Keep this and all other medicines out of the reach of children.

1290 **How do I prepare and inject PEGASYS?**

1291 You should read through all of these directions and ask your healthcare provider for help
1292 if you have any questions before trying to give yourself an injection. It is important to
1293 follow these directions carefully. Talk to your healthcare provider if you have any
1294 questions about PEGASYS.

1295 Your healthcare provider may not want you to take all the medicine that comes in the
1296 prefilled syringe. To appropriately administer the dose that your healthcare provider tells
1297 you to take, you may have to get rid of some of the medicine before injecting the
1298 medicine.

1299 If you ever switch between using prefilled syringes and vials, talk to your healthcare
1300 provider about how much PEGASYS to use. Equal volumes of liquid from the prefilled
1301 syringes and the vials DO NOT contain the same amount of PEGASYS. If you switch
1302 between prefilled syringes and vials, you will have to adjust the volume of liquid that you
1303 use to give your injection. If you do not adjust this, you could accidentally take too much
1304 or too little of your medicine.

1305 If you are giving this injection to someone else, a healthcare provider must teach you how
1306 to avoid needle sticks. Being stuck by a used needle can pass diseases on to you.

1307 The prefilled syringes are used for injecting PEGASYS under the surface of the skin
1308 (subcutaneous).

1309

1310 1. Collect all the materials you will need before you start to give the injection:

1311

1312 • One PEGASYS prefilled syringe Monthly Convenience Pack containing an
1313 inner carton holding the PEGASYS prefilled syringe

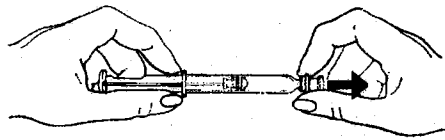
1314 • A puncture-resistant container for cleaning up when you are finished

1315

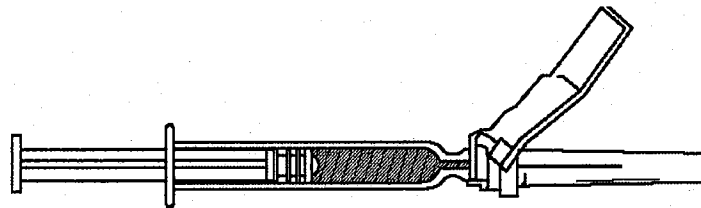
1316 2. Open the convenience pack and look at the contents.

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- 1317 • Each convenience pack has everything you need for the PEGASYS injection.
1318 – 4 single use syringes filled with medicine (should be colorless to light
1319 yellow)
1320 – four 27-gauge, ½-inch needles with needle-stick protection device
1321 – 4 alcohol swabs
1322 • Do not use PEGASYS if:
1323 – the medicine is cloudy
1324 – the medicine has particles floating in it
1325 – the medicine is any color besides colorless to light yellow
1326 – the expiration date has passed
1327 3. Warm the refrigerated medicine by gently rolling it in the palms of your hands for
1328 about one minute. Do not shake.
1329 4. Wash your hands with soap and warm water to prevent infection.
1330 5. Attachment of the needle to the PEGASYS prefilled syringe:
1331 • Remove the needle from its package. Do not remove the needle shield yet.
1332 Keep the needle covered until just before you give the injection.
1333 • Remove and discard the rubber cap from the tip of the syringe barrel.
1334



- 1335
1336 • Put the needle onto the end of the syringe barrel so it fits tightly.
1337 • Here is a picture of the assembled syringe:
1338

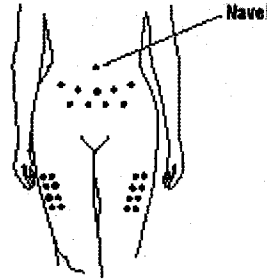


- 1339
1340 • Keep the syringe in a horizontal position until ready for use.
1341 • If you need to set the syringe down, make sure the plastic shield covers the
1342 needle. Never let the needle touch any surface.
1343
1344 6. Decide where you will give the injection.

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- 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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1350

7. Prepare your skin for the injection.

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- To minimize the discomfort from injections, you may want to gently tap the area where you plan to give yourself an injection.

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1353

- Clean the area using the alcohol pad. Let the skin dry for 10 seconds.

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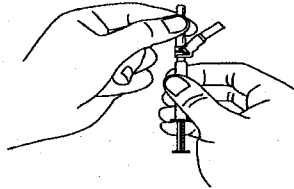
8. Uncover the needle.

1355

- Remove the plastic safety shield covering the needle. Do not remove the green cap that is attached to the end of the syringe and above the needle that is the needle-stick protection device.

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1359

9. Remove air bubbles from the syringe.

1360

- Hold the syringe with the needle pointing up to the ceiling.

1361

- Using your thumb and finger, tap the syringe to bring air bubbles to the top.

1362

- Press the plunger in slightly to push air bubbles out of the syringe.

1363

- Your healthcare provider may not want you to take all the medicine that comes in the prefilled syringe.

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- To appropriately administer the dose that your healthcare provider tells you to take, you may have to get rid of some of the medicine before injecting the medicine.

1366

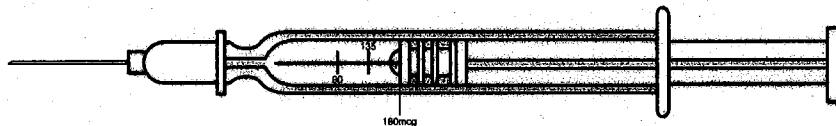
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- The syringe has markings for 180 mcg, 135 mcg, and 90 mcg. Your healthcare provider will tell you which mark to use.

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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

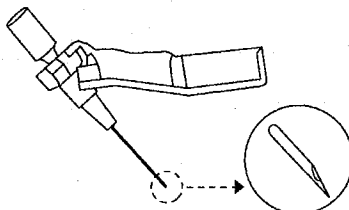
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- 1375 the edge of the plunger stopper reaches the right mark on the side of the
1376 syringe.
1377 • Do not decrease or increase your dose of PEGASYS unless your healthcare
1378 provider tells you to.
1379

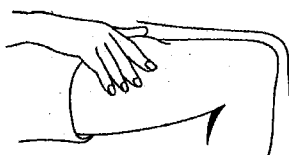
10. Give the injection of PEGASYS.

- 1380
1381 • Position the point of the needle (the bevel) so it is facing up.



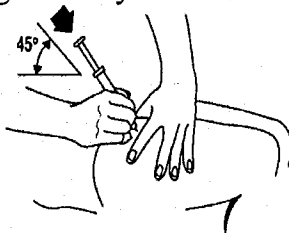
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- 1383 • Pinch a fold of skin on your stomach or thigh firmly with your thumb and
1384 forefinger.



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- 1386 • Hold the syringe like a pencil at a 45° to 90° angle to your skin. In one quick
1387 motion, insert the needle as far as it will go into the pinched area of skin. Pull
1388 the plunger of the syringe back very slightly. If blood comes into the syringe,
1389 the needle has entered a blood vessel. **Do not inject. Withdraw the needle
1390 and discard the syringe as outlined in step 11. Repeat the above steps
1391 with a new prefilled syringe and prepare a new site.**
1392 • If no blood appears, release your skin and slowly push the plunger all the way
1393 down so that you get all of your medicine.



1394

- 1395 • Pull out the needle at same angle you put it in.
1396 • Wipe the area with an alcohol swab.

- 1397 11. For safety reasons, before you dispose of the syringe and needle, place the free end of
1398 the green cap on a flat surface and push down on it until it clicks and covers over the
1399 needle. Always place used syringes and needles in a puncture-resistant container
1400 immediately after use and never reuse them. Keep your disposal container out of the
1401 reach of children.

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1402 **How should I dispose of materials used to inject PEGASYS?**

1403 There may be special state and local laws for disposal of used needles and syringes. Your
1404 healthcare provider or pharmacist should provide you with instructions on how to
1405 properly dispose of your used syringes and needles. Always follow these instructions.

1406 The instructions below should be used as a general guide for proper disposal:

- 1407 • The needles and syringes should never be reused.
- 1408 • Place all used needles and syringes in a puncture-proof disposable container that is
1409 available through your pharmacy or healthcare provider (Sharp's container).
- 1410 • DO NOT use glass or clear plastic containers for disposal of needles and syringes.
- 1411 • Dispose of the full container as instructed by your healthcare provider or pharmacist.

1412

1413 **DO NOT throw the container in your household trash. DO NOT recycle. Keep the**
1414 **container out of the reach of children.**

1415 MG Appendix: Prefilled Syringe revision date: September 2008

1416 **Medication Guide Appendix: Instructions for Preparing and Giving a Dose with a** 1417 **PEGASYS® Vial**

1418 **How should I store PEGASYS vials?**

1419 PEGASYS must be stored in the refrigerator at a temperature of 2°C to 8°C (36°F to
1420 46°F). Do not leave PEGASYS outside of the refrigerator for more than 24 hours. Do not
1421 freeze PEGASYS. Keeping PEGASYS at temperatures outside the recommended range
1422 can destroy the medicine.

1423 Each PEGASYS vial can only be used once. Discard after use.

1424 Do not shake the vial of PEGASYS. If PEGASYS is shaken too hard, it will not work
1425 properly.

1426 Protect PEGASYS from light during storage.

1427 Keep this and all other medicines out of the reach of children.

1428 **How do I inject PEGASYS?**

1429 The following instructions will help you learn how to measure your dose and give
1430 yourself an injection of PEGASYS. You should read through all of these directions and
1431 ask your healthcare provider for help if you have any questions before trying to give
1432 yourself an injection. It is important to follow these directions carefully. Talk to your
1433 healthcare provider if you have any questions about PEGASYS.

1434 If you are giving an injection to someone else, a healthcare provider must teach you how
1435 to avoid needle sticks. Being stuck by a used needle can pass diseases on to you.

1436 1. Collect all the materials you will need before you start to give the injection:

- 1437 • One vial of PEGASYS
- 1438 • One syringe and needle
- 1439 • Several alcohol pads

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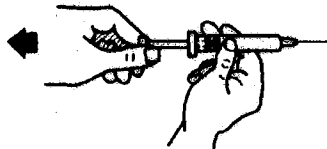
- 1440 • A puncture-resistant container to dispose of the needle and syringe when you are
1441 finished
- 1442 2. Check the date on the carton the PEGASYS comes in and make sure the expiration
1443 date has not passed, then remove a vial from the package and look at the medicine.
- 1444 • Do not use PEGASYS if:
1445 – the medicine is cloudy
- 1446 – the medicine has particles floating in it
- 1447 – the medicine is any color besides colorless to light yellow
- 1448 – the expiration date has passed
- 1449 3. Warm the refrigerated medicine by gently rolling it in the palms of your hands for
1450 about one minute. Do not shake.
- 1451 4. Wash your hands with soap and warm water to prevent infection.
- 1452 5. Take the vial of PEGASYS and flip off the plastic top covering the vial opening, and
1453 clean the rubber stopper on the top of the vial with a different alcohol pad.



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1455 **If you are not sure how much medicine to use or which mark to use, STOP and call**
1456 **your healthcare provider right away.**

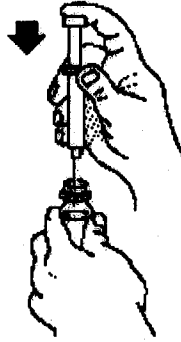
- 1457 6. Remove the needle and syringe from their packaging and attach the needle to the end
1458 of the syringe.
- 1459 • Pull the plunger back so the end of it is to the mark on the syringe barrel that
1460 matches the dose prescribed for you by your healthcare provider. This will pull air
1461 into the syringe barrel.



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- 1463 • Push the needle through the center of the stopper on the vial.
1464 • Slowly inject all the air from the syringe into the air space above the solution. Do
1465 not inject air into the fluid.

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



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

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7. Remove air bubbles from the syringe.

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

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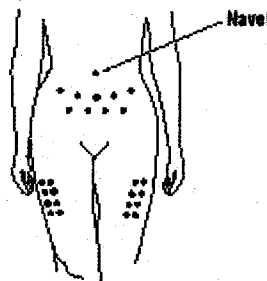
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8. Decide where you will give the injection.

- 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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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.

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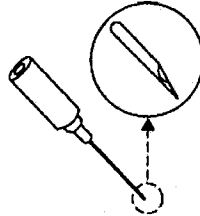
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- Clean the area using an alcohol pad. Let the skin dry for 10 seconds.

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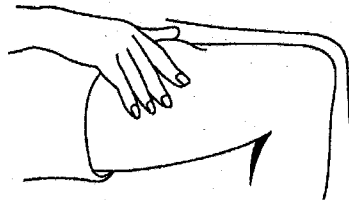
10. Give the injection of PEGASYS.

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



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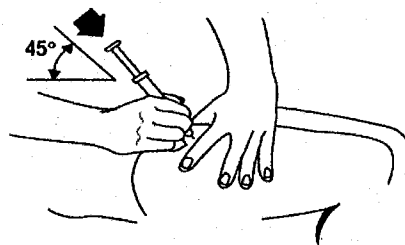
- Pinch a fold of skin on your stomach or thigh firmly between your thumb and forefinger.



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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 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.



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- Pull out the needle at same angle you put it in. Wipe the area with an alcohol pad.

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11. For safety reasons, always place used syringes and needles in a puncture-resistant container immediately after use and never reuse them.

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- 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.

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1515 **How should I dispose of materials used to inject PEGASYS?**

1516 There may be special state and local laws for disposal of used needles and syringes. Your
1517 healthcare provider or pharmacist should provide you with instructions on how to
1518 properly dispose of your used syringes and needles. Always follow these instructions.

1519 The instructions below should be used as a general guide for proper disposal:

- 1520 • The needles and syringes should never be reused.
- 1521 • Place all used needles and syringes in a puncture-proof disposable container that is
1522 available through your pharmacy or healthcare provider (Sharp's container).
- 1523 • DO NOT use glass or clear plastic containers for disposal of needles and syringes.
- 1524 • Dispose of the full container as instructed by your healthcare provider or pharmacist.
1525

1526 **DO NOT throw the container in your household trash. DO NOT recycle. Keep the**
1527 **container out of the reach of children.**

1528 MG Appendix: Vial revision date: October 2008



Pharmaceuticals

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