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MEDICATION GUIDE

Roferon®-A

(Interferon alfa-2a, recombinant)

Solution for Injection – Prefilled Syringes

Before you start taking Roferon-A (ro-FER-on), please read this Medication Guide carefully. Read this Medication Guide each time you refill your prescription in case new information has been added. This information does not take the place of talking with your healthcare provider.

What is the most important information I should know about Roferon-A?

Roferon is used to treat people with hepatitis C, hairy cell leukemia, AIDS-related Kaposi’s sarcoma, and Philadelphia chromosome positive chronic myelogenous leukemia (CML). However, Roferon-A can cause some serious side effects that may cause death in rare cases. Before starting Roferon-A, you should talk with your healthcare provider about the possible benefits and the possible side effects of treatment, to decide if Roferon-A is right for you. While taking Roferon-A, you will need to see your healthcare provider regularly for medical examinations and blood tests to make sure your treatment is working and to check for side effects.

The most serious possible side effects of Roferon-A treatment include:

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

2. **Heart problems:** Roferon-A may cause some patients to experience high blood pressure, a fast heartbeat, chest pain, and very rarely a heart attack. Tell your healthcare provider if you have or have had any heart problems in the past.

39 3. **Blood problems:** Many patients taking Roferon-A have had a drop in the
40 number of their white blood cells and their platelets. If the numbers of
41 these blood cells are too low, you could be at risk for infections or
42 bleeding.

43 **Stop taking Roferon-A and call your healthcare provider immediately if**
44 **you develop any of these symptoms:**

- 45 ● **You become very depressed or think about suicide**
- 46 ● **You have severe chest pain**
- 47 ● **You have trouble breathing**
- 48 ● **You have a change in your vision**
- 49 ● **You notice unusual bleeding or bruising**
- 50 ● **High fever**
- 51 ● **Severe stomach pain. If the pain is in the lower part of your stomach**
52 **area it could mean that your bowels are inflamed (colitis)**

53 *For more information on possible side effects with Roferon-A therapy, please*
54 *read the section on "What are the possible side effects of Roferon-A?" in this*
55 *Medication Guide.*

56 **What is Roferon-A?**

57 Roferon-A is a treatment that is used for some people who are infected with
58 the hepatitis C virus, hairy cell leukemia, AIDS-related Kaposi's sarcoma, and
59 Philadelphia chromosome positive chronic myelogenous leukemia (CML).
60 Patients with hepatitis C have the virus that causes hepatitis in their blood and
61 liver. Patients with hairy cell leukemia produce abnormal white blood cells
62 that travel to the spleen where they trap and destroy normal blood cells. In
63 AIDS-related Kaposi's sarcoma, the virus affects the immune system causing
64 many patients to develop lesions on the skin, in the nose, mouth, and
65 sometimes in the lungs, bowels, and lymph nodes. In CML, your body
66 produces too many of certain blood cells. Roferon-A works in these
67 conditions by reducing the amount of virus in the body, destroying cells that
68 may be harmful to your body and keeping the body from producing too many
69 cells.

70 **Who should not take Roferon-A?**

71 Do not use Roferon-A if:

- 72 ● You are pregnant or breast-feeding or are planning to become pregnant
- 73 ● You are allergic to alpha interferons, *Escherichia coli*-derived products or
74 any component of Roferon-A (see ingredients listed at the end of this
75 Medication Guide)
- 76 ● You have autoimmune hepatitis (hepatitis caused by your immune system
77 attacking your liver)

78

79 **If you have or have had any of the following conditions or serious medical**
80 **problems, discuss them with your doctor before taking Roferon-A:**

- 81 • History of or current severe mental illness (such as depression or anxiety)
- 82 • Previous heart attack or heart problems
- 83 • Sleep problems
- 84 • High blood pressure
- 85 • Autoimmune disease (where the body's immune system attacks the body's
- 86 own cells), such as vasculitis, psoriasis, systemic lupus erythematosus,
- 87 rheumatoid arthritis
- 88 • Kidney problems
- 89 • Blood disorders-Low blood counts or bleeding problems
- 90 • You take a medicine called theophylline
- 91 • Diabetes (high blood sugar)
- 92 • Thyroid problems
- 93 • Liver problems, other than hepatitis C
- 94 • Hepatitis B infection
- 95 • HIV infection (the virus that causes AIDS)
- 96 • Problems with your vision
- 97 • Colitis
- 98 • Body organ transplant and are taking medicine that keeps your body from
- 99 rejecting your transplant (suppresses your immune system)
- 100 • Alcoholism
- 101 • Drug abuse or addiction

102

103 If you have any doubts about your health condition or about taking Roferon-
104 A, talk to your healthcare provider.

105 **What should I avoid while taking Roferon-A?**

- 106 • Avoid becoming pregnant while taking Roferon-A. Roferon-A may harm
- 107 your unborn child or cause you to lose your baby (miscarry)
- 108 • You should not breast-feed your baby while taking Roferon-A

109 **How should I take Roferon-A?**

110 To get the most benefit from this medicine, it is important to take Roferon-A
111 exactly as your healthcare provider tells you.

112 Your healthcare provider will tell you how much medicine to take and how
113 often to take it. Once you start treatment with Roferon-A, do not switch to
114 another brand of interferon without talking to your doctor. Other interferons
115 may not have the same effect on the treatment of your disease. Switching

116 brands will also require a change in your dose. Your healthcare provider will
117 tell you how long you need to use Roferon-A.

118 Over time, your healthcare provider may change your dose of Roferon-A. Do
119 not change your dose unless your doctor tells you to change it.

120 Roferon-A is supplied in vials as a ready-to-use solution and in prefilled
121 syringes. This Medication Guide describes how to use the prefilled syringes.
122 Whether you give yourself the injection or another person gives the injection
123 to you, it is important to follow the instructions in this Medication Guide (see
124 the section, "How do I inject Roferon-A?").

125 If you miss a dose of Roferon-A, take the missed dose as soon as possible
126 during the same day or the next day, then continue on your regular dosing
127 schedule. If several days go by after you miss a dose, check with your doctor
128 about what to do. Do not double the next dose or take more than one dose a
129 day unless your doctor tells you to. Call your doctor right away if you take
130 more than your prescribed Roferon-A dose. Your doctor may wish to
131 examine you more closely and take blood for testing.

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

134 Tell your doctor if you are taking or planning to take other prescription or
135 non-prescription medicines, including vitamins and mineral supplements and
136 herbal medicines.

137 **What are the possible side effects of Roferon-A?**

138 Possible, serious side effects include:

- 139 ● **Mental health problems including suicide, suicidal thoughts, heart**
140 **problems, and blood problems:** See "What is the most important
141 information I should know about Roferon-A?"
- 142 ● **Other body organ problems:** Some patients may experience lung
143 problems (such as difficulty breathing or pneumonia) and vision problems
- 144 ● **New or worsening autoimmune disease:** Some patients may develop an
145 autoimmune disease (a disease where the body's own immune system
146 begins to attack itself) while on Roferon-A therapy. These diseases can
147 include vasculitis (an inflammation of your blood vessels), rheumatoid
148 arthritis or lupus erythematosus, psoriasis or thyroid problems. In some
149 patients who already have an autoimmune disease, the disease may worsen
150 while on Roferon-A therapy

151

152 Common, but less serious, side effects include:

- 153 ● **Flu-like symptoms:** Most patients who take Roferon-A have flu-like
154 symptoms that usually lessen after the first few weeks of treatment. Flu-
155 like symptoms may include unusual tiredness, fever, chills, muscle aches,
156 and joint pain. Taking acetaminophen or ibuprofen before you take

- 157 Roferon-A can help with these symptoms. You can also try taking
158 Roferon-A at night. You may be able to sleep through the symptoms
- 159 • **Extreme fatigue (tiredness):** Many patients may become extremely tired
160 while on Roferon-A therapy
 - 161 • **Upset stomach:** Nausea, taste changes, diarrhea, and loss of appetite
162 occur commonly
 - 163 • **Blood sugar problems:** Some patients may develop a problem with the
164 way their body controls their blood sugar and may develop diabetes
 - 165 • **Thyroid problems:** Some patients may develop changes in their thyroid
166 function. Symptoms of these changes may include feeling hot or cold all
167 the time, trouble concentrating, changes in your skin (your skin may
168 become very dry), and changes in your weight
 - 169 • **Skin reactions:** Some patients may develop a rash, dry or itchy skin, and
170 redness and swelling at the site of injection
 - 171 • **Sleep disturbances and headache:** Trouble sleeping and headaches may
172 also occur during Roferon-A therapy
 - 173 • **Hair thinning:** Hair loss is not uncommon while using Roferon-A. This
174 hair loss is temporary and hair growth should return after you stop taking
175 Roferon-A

176
177 These are not all of the side effects of Roferon-A. Your doctor or pharmacist
178 can give you a more complete list.

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

181 How do I inject Roferon-A?

182 The instructions that follow will help you learn how to use Roferon-A vials
183 and pre-filled syringes. Please read all of these directions before trying to take
184 your medicine. It is important to follow these directions carefully. Talk to
185 your healthcare provider if you have any concerns about how to use Roferon-
186 A. Whether you are giving yourself an injection or if you are giving this
187 injection to someone else, a healthcare provider must teach you how to inject.
188 If you are giving this injection to someone else, a healthcare provider must
189 teach you how to avoid needle-sticks. Being stuck by a used needle can pass
190 diseases on to you.

191 **General advice about prescription medicines**

192 Medicines are sometimes prescribed for purposes other than those listed in a
193 Medication Guide. If you have any concerns or questions about Roferon-A,
194 contact your healthcare provider. Do not use Roferon-A for a condition or
195 person other than that for which it is prescribed. If you want to know more
196 about Roferon-A, your healthcare provider or pharmacist will be able to
197 provide you with detailed information that is written for healthcare providers.

198 **Ingredients:** interferon alfa-2a recombinant, sodium chloride, polysorbate 80,
199 benzyl alcohol, and ammonium acetate.

200 This Medication Guide has been approved by the U.S. Food and Drug
201 Administration.

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APPENDIX: Use of Roferon-A Prefilled Syringes

205 **The prefilled syringes are used for injecting Roferon-A under the surface**
206 **of the skin (subcutaneous).**

207 1 Collect all the materials you will need before you start to give the
208 injection:

- one sterile Roferon-A prefilled syringe with needle

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- alcohol swabs

211

- puncture-resistant disposable container

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2. Check the expiration date on the package to make sure that it has not
213 passed and check the solution in the syringe. The solution in the syringe
214 should be clear or colorless to light yellow in color.

- Do not use Roferon-A if:

the medicine is cloudy

217

the medicine has particles floating in it

218

the medicine is any color besides clear or colorless to light
219 yellow

it has passed the expiration date

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3. Gently warm the refrigerated medicine by slowly rolling the vial in the
222 palms of your hands for about one minute.

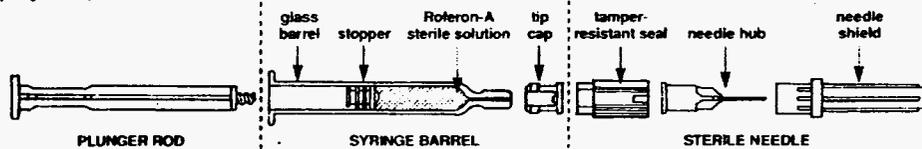
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4. Wash your hands with soap and warm water. This step is very important to
224 help prevent infection.

5. Roferon-A Prefilled syringe:

ASSEMBLY INSTRUCTIONS FOR ROFERON-A PREFILLED SYRINGE

Syringe components:

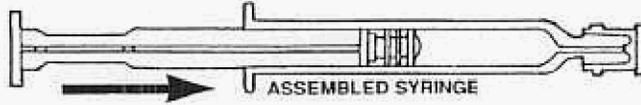


6. Assemble syringe:

- Place plunger rod into open end of syringe barrel

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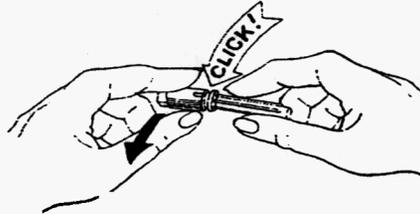
- Gently screw into plunger stopper until snug
DO NOT USE FORCE



7. Prepare the needle:

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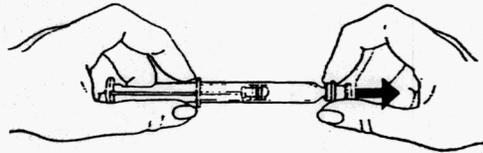
- Turn and pull off bright yellow tamper-resistant seal from needle.
A “click” sound means that the needle is OK to use



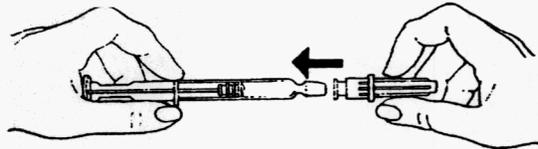
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IF YOU DO NOT HEAR A “CLICK”, DO NOT USE THE NEEDLE
AND DO NOT REMOVE CLEAR NEEDLE SHIELD. DISCARD THE
NEEDLE IN THE PUNCTURE-PROOF CONTAINER

8. To attach the needle to the prefilled syringe:



- Remove grey tip cap from syringe barrel



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- Place the needle onto end of the syringe barrel so it fits snugly. Do
not remove the clear needle shield

9. Choose an injection site:

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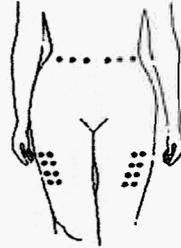
- You should choose a different spot each time you give or receive an injection. The common sites to use are:

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- abdomen, avoiding the navel and waistline area

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- thigh



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- If someone else is giving you the injection, you can use the upper, outer arm



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260 10. Preparing the injection site:

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- Clean the skin where the injection will be given with an alcohol swab and allow the site to dry for 10 seconds

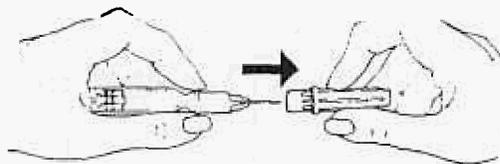
11. Injecting Roferon-A:

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- Hold pale yellow hub between thumb and forefinger and carefully (to avoid a needle-stick) remove clear needle shield with the other hand. The syringe is ready for injection



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- Keep syringe in a horizontal position until ready for use

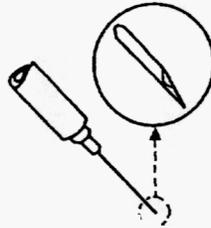


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- Holding the syringe with the needle facing up, tap the syringe barrel to bring air bubbles to surface
- Press plunger slightly to push the air out through the needle

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



- Pinch an area of skin firmly between thumb and forefinger



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- Hold the needle like a pencil at a 45° to 90° angle to skin and using a quick dart-like motion, insert needle as far as it will go



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- Once inserted, draw back slowly on the syringe. If blood appears in the syringe, the needle has entered a blood vessel

288 **Do not inject Roferon-A at that site and discard the syringe. Use a new**
289 **syringe for the injection and use at a different injection site.**

290 ● If blood does not appear in the syringe then slowly push the plunger all the
291 way down so that you get all of your medicine

292 ● Withdraw needle at same angle it was inserted

293 ● When you are finished, place an alcohol swab over the injection site and
294 press slightly



● Place the syringe and needle in a puncture-resistant container

297 ● Do not reuse syringes and needles. Use a new prefilled syringe and
298 needle for each injection

299 **How should I dispose of materials used to inject Roferon-A?**

300 ● Do not recap the needle

301 ● Place the entire syringe and needle in a puncture-resistant container. A
302 home “Sharps Container” may be purchased at your pharmacy or you can
303 use a hard plastic container with a screw top or a coffee can with a plastic
304 lid. You should talk to your healthcare provider about how to properly
305 dispose of a full container of used syringes. There may be special state or
306 local laws about disposing used syringes and needles, so please check with
307 your physician, nurse or pharmacist for instructions. DO NOT throw the
308 filled container in the household trash and DO NOT recycle

309 ● The needle cover and alcohol swabs can be thrown in the regular trash.
310 You should always keep your syringes and disposal container out of the
311 reach of children

312

313 **How should I store Roferon-A?**

314 Roferon-A must be stored in the refrigerator at a temperature of 36°F to 46°F
315 (2°C to 8°C). Do not leave Roferon-A outside of the refrigerator for more than
316 24 hours. Do not freeze Roferon-A. Keeping Roferon-A at temperatures
317 outside the recommended range can destroy the medicine.

318 Do not shake Roferon-A. Shaking can destroy Roferon-A so that it will not
319 work.

Protect Roferon-A from light during storage.

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

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R_x only



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