

6 million IU Roferon-A per syringe — Each 0.5 mL contains 6 MIU of Interferon alfa-2a, recombinant, 3.605 mg sodium chloride, 0.1 mg polysorbate 80, 5 mg benzyl alcohol as a preservative and 0.385 mg ammonium acetate. Boxes of 1 (NDC 0004-2016-09); Boxes of 6 (NDC 0004-2016-07).

9 million IU Roferon-A per syringe — Each 0.5 mL contains 9 MIU of Interferon alfa-2a, recombinant, 3.605 mg sodium chloride, 0.1 mg polysorbate 80, 5 mg benzyl alcohol as a preservative and 0.385 mg ammonium acetate. Boxes of 1 (NDC 0004-2017-09); Boxes of 6 (NDC 0004-2017-07).

### Storage

The prefilled syringe should be stored in the refrigerator at 36° to 46°F (2° to 8°C). Do *not* freeze or shake. Protect Roferon-A from light during storage.

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Revised: January 2008

### MEDICATION GUIDE

#### Roferon<sup>®</sup>-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-A is used to treat people with hepatitis C, hairy cell leukemia 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.

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

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

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

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

**What is Roferon-A?**

Roferon-A is a treatment that is used for some people who are infected with the hepatitis C virus, hairy cell leukemia, and Philadelphia chromosome positive chronic myelogenous leukemia (CML). Patients with hepatitis C have the virus that causes hepatitis in their blood and liver. Patients with hairy cell leukemia produce abnormal white blood cells that travel to the spleen where they trap and destroy normal blood cells. In CML, your body produces too many of certain blood cells. Roferon-A works in these conditions by reducing the amount of virus in the body, destroying cells that may be harmful to your body and keeping the body from producing too many cells.

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

Do not use Roferon-A if:

- You are pregnant or breast-feeding or are planning to become pregnant.
- You are allergic to alpha interferons, *Escherichia coli*-derived products or any component of Roferon-A.
- You have autoimmune hepatitis (hepatitis caused by your immune system attacking your liver).

Roferon-A should not be given to newborn or premature infants.

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

- History of or current severe mental illness (such as depression or anxiety)
- Previous heart attack or heart problems
- Sleep problems
- High blood pressure
- Autoimmune disease (where the body's immune system attacks the body's own cells), such as vasculitis, psoriasis, systemic lupus erythematosus, rheumatoid arthritis
- Kidney problems
- Blood disorders-Low blood counts or bleeding problems
- You take a medicine called theophylline
- Diabetes (high blood sugar)
- Thyroid problems
- Liver problems, other than hepatitis C
- Hepatitis B infection

- HIV infection (the virus that causes AIDS)
- Problems with your vision
- Colitis
- Body organ transplant and are taking medicine that keeps your body from rejecting your transplant (suppresses your immune system)
- Alcoholism
- Drug abuse or addiction

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

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

- Female patients as well as female partners of male patients must avoid becoming pregnant while taking Roferon-A. Roferon-A may harm your unborn child or cause you to lose your baby (miscarry).
- You should not breast-feed your baby while taking Roferon-A.

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

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

Your healthcare provider will tell you how much medicine to take and how often to take it. Once you start treatment with Roferon-A, do not switch to another brand of interferon without talking to your doctor. Other interferons may not have the same effect on the treatment of your disease. Switching brands will also require a change in your dose. Your healthcare provider will tell you how long you need to use Roferon-A.

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

Roferon-A is supplied in prefilled syringes. Whether you give yourself the injection or another person gives the injection to you, it is important to follow the instructions in this Medication Guide (see the appendix "Instructions for Preparing and Giving a Dose with a Roferon-A Prefilled Syringe").

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

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

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

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

Possible, serious side effects include:

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

Common, but less serious, side effects include:

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

- **Blood sugar problems:** Some patients may develop a problem with the way their body controls their blood sugar and may develop diabetes.
- **Thyroid problems:** Some patients may develop changes in their thyroid function. Symptoms of these changes may include feeling hot or cold all the time, trouble concentrating, changes in your skin (your skin may become very dry), and changes in your weight.
- **Skin reactions:** Some patients may develop a rash, dry or itchy skin, and redness and swelling at the site of injection.
- **Sleep disturbances and headache:** Trouble sleeping and headaches may also occur during Roferon-A therapy.
- **Hair thinning:** Hair loss is not uncommon while using Roferon-A. This hair loss is temporary and hair growth should return after you stop taking Roferon-A.

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

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

### **General advice about prescription medicines**

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

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

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

Revised: October 2004

## **Medication Guide Appendix: Instructions for Preparing and Giving a Dose with a Roferon-A Prefilled Syringe**

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

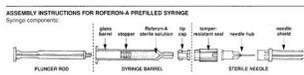
Roferon-A must be stored in the refrigerator at a temperature of 36°F to 46°F (2°C to 8°C). Do not leave Roferon-A outside of the refrigerator for more than 24 hours. Do not freeze Roferon-A. Keeping Roferon-A at temperatures outside the recommended range can destroy the medicine. Do not shake Roferon-A. Shaking can destroy Roferon-A so that it will not work. Protect Roferon-A from light during storage.

### **How do I inject Roferon-A?**

The instructions that follow will help you learn how to use Roferon-A prefilled syringes. Please read all of these directions before trying to take your medicine. It is important to follow these directions carefully. Talk to your healthcare provider if you have any concerns about how to use Roferon-A. Whether you are giving yourself an injection or if you are giving this injection to someone else, a healthcare provider must teach you how to inject.

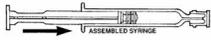
### **The prefilled syringes are used for injecting Roferon-A under the surface of the skin (subcutaneous).**

1. Collect all the materials you will need before you start to give the injection:
  - one sterile Roferon-A prefilled syringe with needle
  - alcohol swabs
  - puncture-resistant disposable container
2. Check the expiration date on the package to make sure that it has not passed and check the solution in the syringe. The solution in the syringe should be clear or colorless to light yellow in color.
  - Do not use Roferon-A if:
    - the medicine is cloudy
    - the medicine has particles floating in it
    - the medicine is any color besides clear or colorless to light yellow
    - it has passed the expiration date
3. Warm the refrigerated medicine by gently rolling the syringe in the palms of your hands for about one minute.
4. Wash your hands with soap and warm water. This step is very important to help prevent infection.
5. Roferon-A prefilled syringe:



6. Assemble syringe:
  - Place the plunger rod into the open end of the syringe barrel.
  - Gently screw the rod into the plunger stopper until snug.

DO NOT USE FORCE.



7. Prepare the needle:

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



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

If you have another needle, proceed again with Step 7. If no alternate needle is available, contact your healthcare provider to make arrangements for a replacement needle.

8. To attach the needle to the prefilled syringe:



- Remove the grey tip cap from syringe barrel.



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

9. Choose an injection site:

- You should choose a different spot each time you give or receive an injection. The common sites to use are:
- abdomen, avoiding the navel and waistline area
- thigh



- If someone else is giving you the injection, then the upper, outer arm can be used as an injection site.

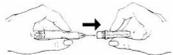


10. Preparing the injection site:

- 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:

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



- Keep the syringe in a horizontal position until ready for use.



- Holding the syringe with the needle facing up, tap the syringe barrel to bring air bubbles to the top.
- Press the plunger slightly to push the air bubbles out through the needle.
- Hold the syringe horizontally, and position the bevel of the needle so the point of the needle is facing up.



- Pinch an area of skin firmly between your thumb and forefinger.



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



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

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

- If blood does not appear in the syringe then slowly push the plunger all the way down so that you get all of your medicine.
- Withdraw the needle at same angle it was inserted. See instructions for disposal of the needle and syringe in the section "How should I dispose of materials used to inject Roferon-A?".
- When you are finished, place an alcohol swab over the injection site and press slightly.



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

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

- Do not recap the needle.
- Place the entire syringe and needle in a puncture-resistant container. A home "Sharps Container" may be purchased at your pharmacy or you can use a hard plastic container with a screw top or a coffee can with a plastic lid. You should talk to your healthcare provider about how to properly dispose of a full container of used syringes. There may be special state or local laws about disposing used syringes and needles, so please check with your physician, nurse or pharmacist for instructions. **DO NOT** throw the filled container in the household trash and **DO NOT** recycle.
- The needle cover and alcohol swabs can be thrown in the regular trash. You should always keep your syringes and disposal container out of the reach of children.

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