MEDICATION GUIDE

Ribavirin

Tablets

Read this Medication Guide carefully before you start taking ribavirin and read the Medication Guide each time you get more ribavirin. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

Also read the Medication Guide for PEGASYS[1] (peginterferon alfa-2a).

What is the most important information I should know about ribavirin?

- **You should not take ribavirin alone to treat chronic hepatitis C infection**. Ribavirin should be used with peginterferon alfa-2a to treat chronic hepatitis C infection.
- **Ribavirin may cause you to have a blood problem (hemolytic anemia) that can worsen any heart problems you have, and cause you to have a heart attack or die.** Tell your healthcare provider if you have ever had any heart problems. Ribavirin may not be right for you. If you have chest pain while you take Ribavirin, get emergency medical attention right away.
- **Ribavirin may cause birth defects or death of your unborn baby.** If you are pregnant or your sexual partner is pregnant, do not take ribavirin. You or your sexual partner should not become pregnant while you take ribavirin and for 6 months after treatment is over. You must use two forms of birth control when you take ribavirin and for the 6 months after treatment.

    1. Females must have a pregnancy test before starting ribavirin, every month while treated with ribavirin, and every month for the 6 months after treatment with ribavirin.
    2. **If you or your female sexual partner becomes pregnant** while taking ribavirin or within 6 months after you stop taking ribavirin, tell your healthcare provider right away. You or your healthcare provider should contact the **Ribavirin Pregnancy Registry by calling 1-800-593-2214**. The Ribavirin Pregnancy Registry collects information about what happens to mothers and their babies if the mother takes ribavirin while she is pregnant.

What is ribavirin?

Ribavirin is a prescription medicine used with another medicine called peginterferon alfa-2a to treat chronic (lasting a long time) hepatitis C infection in people 5 years and older whose liver still works normally, and who have not been treated before with a medicine called an interferon alpha. It is not known if ribavirin is safe and will work in children under 5 years of age.

Who should not take ribavirin?

See "What is the most important information I should know about ribavirin?"

Do not take ribavirin if you:

- **have certain types of hepatitis** caused by your immune system attacking your liver (autoimmune hepatitis)
- **have certain blood disorders, such as thalassemia major or sickle-cell anemia (hemoglobinopathies)**
- **take didanosine** (Videx ®[2] or Videx EC ®[2])

Talk to your healthcare provider before starting treatment with ribavirin if you have any of these medical conditions.

What should I tell my healthcare provider before taking ribavirin?

Before you take ribavirin, tell your healthcare provider if you have or have had:

- **treatment for hepatitis C that did not work for you**
- **serious allergic reactions to ribavirin or to any of the ingredients in ribavirin.** See the end of this Medication Guide for a list of ingredients.
- **breathing problems.** Ribavirin may cause or worsen your breathing problems you already have.
- **vision problems**. Ribavirin may cause eye problems or worsen eye problems you already have. You should have an eye exam before you start treatment with ribavirin.
- **certain blood disorders such as anemia**
- **high blood pressure, heart problems or have had a heart attack**. Your healthcare provider should test your blood and heart before you start treatment with ribavirin.
- **thyroid problems**
- **diabetes.** Ribavirin and peginterferon alfa-2a combination therapy may make your diabetes worse or harder to treat.
- **liver problems** other than hepatitis C virus infection
- **human immunodeficiency virus (HIV) or other immunity problems**
- **mental health problems,** including depression or thoughts of suicide
- **kidney problems**
- **an organ transplant**
- **drug addiction or abuse**
- **infection with hepatitis B virus**
- **any other medical condition**
- **are breast feeding.** It is not known if ribavirin passes into your breast milk. You and your healthcare provider should decide if you will take ribavirin or breast-feed.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements. Some medicines can cause serious side effects if taken while you also take ribavirin. Some medicines may affect how ribavirin works or ribavirin may affect how your other medicines work.

Especially tell your healthcare provider if you take any medicines to treat HIV, including didanosine Videx®[2] or Videx EC®[2]), or if you take azathioprine (Imuran®[3] or Azasan®[4]).

Know the medicines you take. Keep a list of them to show your healthcare provider or pharmacist when you get a new medicine.

How should I take ribavirin?

- Take ribavirin exactly as your healthcare provider tells you. Your healthcare provider will tell you how much ribavirin to take and when to take it. For children 5 years of age and older your healthcare provider will prescribe the dose of ribavirin based on weight.
- Take ribavirin with food.
- If you miss a dose of ribavirin, take the missed dose as soon as possible during the same day. Do not double the next dose. If you have questions about what to do, call your healthcare provider.
- If you take too much ribavirin, call your healthcare provider or local Poison Control Center right away, or go to the nearest hospital emergency room right away.
- Your healthcare provider should do blood tests before you start treatment with ribavirin, at weeks 2 and 4 of treatment, and then as needed to see how well you are tolerating treatment and to check for side effects. Your healthcare provider may change your dose of ribavirin based on blood test results or side effects you may have.

- If you have heart problems, your healthcare provider should check your heart by doing an electrocardiogram before you start treatment with ribavirin, and if needed during treatment.

What should I avoid while taking ribavirin?

- **Ribavirin can make you feel tired, dizzy, or confused. You should not drive or operate machinery if you have any of these symptoms.**
- **Do not drink alcohol,** including beer, wine, and liquor. This may make your liver disease worse.

What are the possible side effects of ribavirin?

Ribavirin may cause serious side effects including:

See "What is the most important information I should know about ribavirin?"

- **Swelling and irritation of your pancreas (pancreatitis).** You may have stomach pain, nausea, vomiting or diarrhea.
- **Severe allergic reactions.** Symptoms may include hives, wheezing, trouble breathing, chest pain, swelling of your mouth, tongue, or lips, or severe rash.
- **Serious breathing problems.** Difficulty breathing may be a sign of a serious lung infection (pneumonia) that can lead to death.
- **Serious eye problems** that may lead to vision loss or blindness.
- **Liver problems.** Some people may get worsening of liver function. Tell your healthcare provider right away if you have any of these symptoms: stomach bloating, confusion, brown urine, and yellow eyes.
- **Severe depression**
- **Suicidal thoughts and attempts**
- **Effect on growth in children.** Children can experience a delay in weight gain and height increase while being treated with peginterferon alfa-2a and ribavirin. Catch-up in growth happens after treatment stops, but some children may not reach the height that they were expected to have before treatment. Talk to your healthcare provider if you are concerned about your child's growth during treatment with peginterferon alfa-2a and ribavirin.

Call your healthcare provider or get medical help right away if you have any of the symptoms listed above. These may be signs of a serious side effect of ribavirin treatment.

Common side effects of ribavirin taken with peginterferon alfa-2a include:

- flu-like symptoms-feeling tired, headache, shaking along with high temperature (fever), and muscle or joint aches
- mood changes, feeling irritable, anxiety, and difficulty sleeping
- loss of appetite, nausea, vomiting, and diarrhea
- hair loss
- itching

Tell your healthcare provider about any side effect that bothers you or that does not go away.

These are not all the possible side effects of ribavirin treatment. For more information, ask your healthcare provider or pharmacist.

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

You may also report side effects to Richmond Pharmaceuticals, Inc. at 804-270-4498.

How should I store ribavirin?

- Store ribavirin tablets between 59°F and 86°F (15°C and 30°C).
- Keep the bottle tightly closed.

Keep ribavirin and all medicines out of the reach of children.

General information about the safe and effective use of ribavirin

It is not known if treatment with ribavirin in combination with peginterferon alfa-2a will prevent an infected person from spreading the hepatitis C virus to another person while on treatment.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ribavirin for a condition for which it was not prescribed. Do not give ribavirin to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about ribavirin. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about ribavirin that is written for healthcare professionals.

What are the ingredients in ribavirin?

Active Ingredient: ribavirin

Inactive Ingredients: microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, povidone, magnesium stearate, and purified water. The tablet is coated with partially hydrolyzed polyvinyl alcohol, polyethylene glycol 3350, talc, titanium dioxide, FD&C blue #2 [indigo carmine aluminum lake] (200 mg tablet only), FD&C blue #1 [brilliant blue FCF aluminum lake] (400 mg and 600 mg tablets only), and carnauba wax.

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

[1] PEGASYS is a trademark of Hoffmann-La Roche Inc.

[2] Videx and Videx EC is a registered trademark of Bristol-Myers Squibb Company

[3] Imuran is a registered trademark of Prometheus Laboratories, Inc.

[4] Azasan is a registered trademark of Salix Pharmaceuticals, Inc.

Manufactured by

PATHEON MANUFACTURING SERVICES, LLC

Greenville, NC 27834, USA

for

RICHMOND PHARMACEUTICALS, INC.

Richmond, VA 23233, USA

Printed in USA

U.S. Patent No. 7,723,310

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C108.00160 v2.0 C108.00174 v1.1

Revised: 9/2017