

# Ribasphere® RibaPak® (ribavirin, USP) Tablets

This summary contains important information about Ribasphere® (Rīb-ā-sphere) (ribavirin, USP) tablets. It is not meant to take the place of your doctor's and/or healthcare provider's instructions. Read this information carefully before you start taking Ribasphere. Ask your doctor and/or healthcare provider if you do not understand any of this information, or if you want to know more about Ribasphere. Read the Medication Guide given to you for Ribasphere. Also read the Medication Guide for PEGASYS® (peginterferon alfa-2a).

## WARNING: RISK OF SERIOUS DISORDERS AND RIBASPHERE ASSOCIATED EFFECTS

See full Prescribing Information for complete boxed warning

- You should not take Ribasphere alone to treat chronic hepatitis C infection.
- Ribasphere 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. People with a history of serious heart disease should not be treated with this medicine. Please talk to your health care professional to see if this medicine is right for you.
- Ribasphere may cause birth defects or death of your unborn baby. You should not take Ribasphere if you are pregnant or your sexual partner is pregnant, nor should you or your partner become pregnant while you are taking Ribasphere and for 6 months after you stop treatment. You need to use two forms of reliable birth control when you take Ribasphere and for the 6 months after treatment.

### What is Ribasphere?

Ribasphere (ribavirin, USP) tablets are used in combination with another medicine called peginterferon alfa-2a to treat chronic (lasting a long time) hepatitis C infection (CHC) in people 5 years and older whose livers still work normally, and who have not been treated before with a medicine called an interferon alpha. This combination is also used to treat CHC patients coinfecting with human immunodeficiency virus (HIV). It is not known if Ribasphere is safe and will work in children under 5 years of age.

### Who should not take Ribasphere?

#### Do not take Ribasphere 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);
- have severe kidney disease; or
- take didanosine (Videx® or Videx EC®).

### Important information about Ribasphere:

1. **You should not take Ribasphere alone to treat chronic hepatitis C infection.** Ribasphere should be used in combination with peginterferon alfa-2a to treat chronic hepatitis C infection.
2. **Ribasphere 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. Ribasphere may not be right for you. If you have chest pain while you take Ribasphere, seek emergency medical attention right away.
3. **Ribasphere may cause birth defects or death of your unborn baby.** If you are pregnant or your sexual partner is pregnant, do not take Ribasphere. You or your sexual partner should not become pregnant while you take Ribasphere and for 6 months after treatment is over. You must use two forms of birth control when you take Ribasphere and for the 6 months after treatment.
  - **Females must have a pregnancy test before starting Ribasphere**, every month while treated with Ribasphere, and every month for the 6 months after treatment with Ribasphere.
  - **If you or your female sexual partner becomes pregnant** while taking Ribasphere or within 6 months after you stop taking Ribasphere, 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 Ribasphere while she is pregnant.

### What are the possible side effects of Ribasphere?

#### Ribasphere can cause serious side effects including:

- **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:** Which could 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;** and/or
- **effect on growth in children.** Children can experience a delay in weight gain and height increase while being treated with peginterferon alfa-2a and Ribasphere. 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 Ribasphere.

**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 Ribasphere treatment.**

### Common side effects of Ribasphere used in combination with peginterferon alfa-2a include:

- flu-like symptoms (for example: 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; and/or
- itching.

### Before you take Ribasphere, tell your healthcare provider if you are, have, or have had:

- **treatment for hepatitis C that did not work for you;**
- **serious allergic reactions to Ribasphere, or to any of the ingredients in Ribasphere;**
- **breathing problems** (Ribasphere may cause or worsen your breathing problems you already have.);
- **vision problems** (Ribasphere may cause eye problems or worsen eye problems you already have. You should have an eye exam before you start treatment with Ribasphere.);
- **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 Ribasphere.);
- **thyroid problems;**
- **diabetes** (Ribasphere 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 the hepatitis B virus;**
- **breast feeding** (It is not known if Ribasphere passes into your breast milk. You and your healthcare provider should decide if you will take Ribasphere or breast-feed.); and/or
- **any other medical condition.**

### How should you take Ribasphere?

- Take Ribasphere exactly as your healthcare provider tells you. Your healthcare provider will tell you how much Ribasphere to take and when to take it. For children 5 years of age and older your healthcare provider will prescribe the dose of Ribasphere based on weight.
- Take Ribasphere with food.
- If you miss a dose of Ribasphere, 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 Ribasphere, 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 Ribasphere, 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 Ribasphere 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 Ribasphere, and if needed during treatment.

### What should you avoid while taking Ribasphere?

- **Ribasphere 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.

### Medicine interactions:

**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 Ribasphere. Some medicines may affect how Ribasphere works or Ribasphere may affect how your other medicines work. Especially tell your healthcare provider if you take any medicines to treat HIV, including didanosine (Videx® or Videx EC®), or if you take azathioprine (Imuran® or Azasan®).

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

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.**

**Please see Ribasphere full Prescribing Information and Medication Guide, including boxed warning, for additional Important Safety Information. Visit [www.ribapak.com](http://www.ribapak.com), or call 1-877-377-7862.**

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