

**RIBASPHERE®**, (ribavirin, USP) TABLETS,  
200 mg, 400 mg, and 600 mg  
Rx Only

Read this Medication Guide carefully before you start taking RIBASPHERE (Rib-a-sphere) and read the Medication Guide each time you get more RIBASPHERE. 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.

**What is the most important information I should know about RIBASPHERE?**

**1. RIBASPHERE, a form of ribavirin, may cause birth defects or death of an unborn child. Therefore, if you are pregnant or your partner is pregnant or plans to become pregnant, do not take RIBASPHERE.** Female patients and female partners of male patients being treated with RIBASPHERE must not become pregnant during treatment and for 6 months after treatment has stopped.

**During this time you must have pregnancy tests that show you are not pregnant. You must also use 2 effective forms of birth control during therapy and for 6 months after stopping therapy.** Male patients should use a condom with spermicide as one of the two forms.

If pregnancy occurs, report the pregnancy to your healthcare provider right away. (See **"What should I avoid while taking RIBASPHERE?"**.)

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

**2. RIBASPHERE can cause a dangerous drop in your red blood cell count.**

RIBASPHERE can cause anemia, which is a decrease in the number of red blood cells. This can be dangerous, especially if you have heart or breathing problems. This may cause a worsening of heart (cardiovascular) or circulatory problems. Some patients may get chest pain and rarely, a heart attack. Patients with a history of heart disease have the highest chance of this. Tell your healthcare provider, before taking RIBASPHERE if you have or have ever had any heart or breathing problems. Your healthcare provider should check your red blood cell count before you start treatment with RIBASPHERE and often during the first 4 weeks of treatment. Your red blood cell count may be done more often if you have any heart or breathing problems.

**3. Do not take RIBASPHERE alone to treat hepatitis C virus infection.**

RIBASPHERE does not treat hepatitis C virus infections by itself. RIBASPHERE should be used in combination with PEGASYS®<sup>1</sup> (peginterferon alfa-2a) to treat continuing (chronic) hepatitis C virus infections. You should read the Medication Guide for PEGASYS because it has additional important information about treatment that is not covered in this Medication Guide. Your healthcare provider or pharmacist should give you a copy of the PEGASYS Medication Guide.

**What is RIBASPHERE?**

RIBASPHERE is the antiviral medicine ribavirin. It is used in combination with a medicine called peginterferon alfa-2a to treat some adults with chronic hepatitis C whose liver still works normally, and who have not been treated before with a medicine called an interferon alpha. It is not known how RIBASPHERE and peginterferon alfa-2a work together to fight hepatitis C virus infections.

It is not known if treatment with RIBASPHERE and peginterferon alfa-2a combination therapy can cure hepatitis C or if it can prevent liver damage (cirrhosis), liver failure or liver cancer that is caused by hepatitis C virus infections. It is not known if treatment with RIBASPHERE and peginterferon alfa-2a combination therapy will prevent an infected person from spreading the hepatitis C virus to another person.

Treatment with RIBASPHERE has not been studied in children under 18 years of age.

**Who should not take RIBASPHERE?**

**Do not use RIBASPHERE if:**

- You are a female and you are pregnant or plan to become pregnant during

treatment or during the 6 months after your treatment has ended. (See **"What is the most important information I should know about RIBASPHERE?"** and **"What should I avoid while taking RIBASPHERE?"**)

- You are a male patient with a female sexual partner who is pregnant or plans to become pregnant at any time while you are being treated with RIBASPHERE or during the 6 months after your treatment has ended. (See **"What is the most important information I should know about RIBASPHERE?"** and **"What should I avoid while taking RIBASPHERE?"**)
- You are breast feeding. We do not know if RIBASPHERE can pass through your milk and if it can harm your baby. You will need to choose either to breast-feed or take RIBASPHERE, but not both.
- You have a liver disease called autoimmune hepatitis (hepatitis caused by your immune system attacking your liver).
- You have unstable or severe liver disease.
- You are allergic to any of the ingredients in RIBASPHERE. The active ingredient in RIBASPHERE is ribavirin. See the end of this Medication Guide for a list of all the ingredients in RIBASPHERE.

**Tell your healthcare provider before starting treatment with RIBASPHERE in combination with peginterferon alfa-2a (see also the PEGASYS Medication Guide) if you have any of the following medical conditions:**

- **mental health problems, such as depression or anxiety:** RIBASPHERE and peginterferon alfa-2a combination therapy may make them worse. Tell your healthcare provider if you are being treated or had treatment in the past for any mental problems, including depression, thoughts of ending your life (suicidal thoughts) or a feeling of loss of contact with reality, such as hearing voices or seeing things that are not there (psychosis). Tell your healthcare provider if you take any medicines for these problems.
- **high blood pressure, heart problems or have had a heart attack.** RIBASPHERE may worsen heart problems such as high blood pressure, increased heart rate, and chest pain. Tell your healthcare provider if you have or had a heart problem. Patients who have had certain heart problems should not take RIBASPHERE.
- **blood disorders**, including anemia (low red blood cell count), thalassemia (Mediterranean anemia) and sickle-cell anemia. RIBASPHERE can reduce the number of red blood cells you have. This may make you feel dizzy or weak and could worsen any heart problems you might have.
- **kidney problems.** If your kidneys do not work properly, you may have worse side effects from RIBASPHERE treatment and require a lower dose.
- **liver problems** (other than hepatitis C virus infection).
- **organ transplant**, and you are taking medicine that keeps your body from rejecting your transplant (suppresses your immune system).
- **thyroid disease.** RIBASPHERE and peginterferon alfa-2a combination therapy may make your thyroid disease worse or harder to treat. RIBASPHERE and peginterferon alfa-2a treatment may be stopped if you develop thyroid problems that cannot be controlled by medicine.
- **have or had drug or alcohol addiction or abuse.**
- **cancer.**
- **infection with hepatitis B virus.**
- **diabetes.** RIBASPHERE and peginterferon alfa-2a combination therapy may make your diabetes worse or harder to treat.
- **past interferon treatment for hepatitis C virus infection that did not work for you.**

**Tell your healthcare provider about all the medicines you take**, including prescription and non-prescription medicines, vitamins or 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. Be especially sure to tell your healthcare provider if you take any medicines to treat HIV.

**For more information see the PEGASYS Medication Guide.**

**How should I take RIBASPHERE?**

- Your healthcare provider will determine the right dose of RIBASPHERE based on your weight.
- Take RIBASPHERE 1 time in the morning and 1 time at night (2 times a day). Take RIBASPHERE the same 2 times each day.
- Take RIBASPHERE with food.
- It is very important to follow your dosing schedule and your healthcare provider's instructions on how to take your medicines.

- Take RIBASPHERE for as long as it is prescribed, and do not take more than your healthcare provider prescribes.
- If you miss a dose of RIBASPHERE and remember **the same day**, take the missed dose as soon as you remember. If **the whole day has passed**, ask your healthcare provider what to do. Do not take 2 doses at the same time.
- Your healthcare provider may adjust your dose of RIBASPHERE based on blood tests that show your response to treatment and side effects you may have.
- **Females taking RIBASPHERE or female sexual partners of male patients taking RIBASPHERE must have a pregnancy test:**
  - before treatment begins
  - every month during treatment
  - for 6 months after treatment ends to make sure there is no pregnancy

It is also important not to use other ribavirin medicines without talking to your healthcare provider. Please see the PEGASYS Medication Guide for the proper use of PEGASYS injection.

### What should I avoid while taking RIBASPHERE?

#### **Avoid the following during RIBASPHERE treatment:**

- **Do not get pregnant.** If you or your sexual partner get pregnant during treatment with RIBASPHERE or in the 6 months after treatment ends, tell your healthcare provider right away. (See "**What is the most important information I should know about treatment with RIBASPHERE?**")

Talk with your healthcare provider about birth control methods and how to avoid pregnancy. You must use extreme care to avoid pregnancy during and for 6 months after treatment in female and male patients.

- **Do not take RIBASPHERE alone to treat your hepatitis C virus infection.** RIBASPHERE should be used in combination with peginterferon alfa-2a to treat chronic hepatitis C virus infections. (See "**What is the most important information I should know about treatment with RIBASPHERE?**")
- **Do not breast feed.** RIBASPHERE may pass through your milk and may harm your baby.
- **Do not drink alcohol**, including beer, wine, and liquor. This may make your liver disease worse.
- **Do not drive or operate machinery** if RIBASPHERE makes you feel tired, dizzy or confused.
- **Do not take other medicines unless your healthcare provider knows about them.** Take only medicines prescribed or approved by your healthcare provider. These include prescription and non-prescription medicines, vitamins or herbal supplements. Talk to your healthcare provider before starting any new medicine.

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

#### **The most serious possible side effects of RIBASPHERE are:**

- **Harm to unborn children.** RIBASPHERE may cause birth defects or death of an unborn child. (For more details, see "**What is the most important information I should know about RIBASPHERE?**")
- **Anemia.** Anemia is a reduction in the number of red blood cells you have. Anemia can be dangerous, especially if you have heart or breathing problems. Tell your healthcare provider right away if you feel tired, have chest pain or shortness of breath. These may be signs of low red blood cell counts.
- **Liver Problems.** Some patients may develop worsening of liver function. Some of the symptoms may include stomach bloating, confusion, brown urine, and yellow eyes. Tell your healthcare provider immediately if any of these symptoms occur.

**Call your healthcare provider right away if you have any of the following symptoms. They may be signs of a serious side effect of RIBASPHERE and peginterferon alfa-2a treatment.**

- trouble breathing
- hives or swelling
- chest pain
- severe stomach pain or low back pain
- bloody diarrhea or bloody stools (bowel movements). These may look like black tar.
- bruising or unusual bleeding
- change in your vision
- high fever (temperature greater than 100.5°F)
- you have psoriasis (a skin disease) and it gets worse
- you become very depressed or think about suicide (ending your life)

### The most common side effects of RIBASPHERE are likely to be the same as for other ribavirin products. These are:

- feeling tired
- nausea and appetite loss
- rash and itching
- cough

These are not all the possible side effects of RIBASPHERE treatment. For more information, ask your doctor or pharmacist and see the PEGASYS Medication Guide.

### What should I know about hepatitis C infection?

Hepatitis C infection is a disease caused by a virus that infects the liver. Hepatitis C is more serious for some people than others. Most people who get hepatitis C carry the virus in their blood for the rest of their lives. Most of these people will have some liver damage, but many do not feel sick from the disease. In some people, the liver becomes badly damaged and scarred. This is called cirrhosis. Cirrhosis can cause the liver to stop working. Some people may get liver cancer or liver failure from the hepatitis C virus.

Hepatitis C virus is spread from one person to another by contact with an infected person's blood. You should talk to your healthcare provider about ways to prevent you from infecting others.

### How should I store RIBASPHERE?

Store RIBASPHERE tablets at 25°C (77°F); excursions permitted to 15° and 30°C (59° and 86°F). Keep bottle tightly closed.

Please refer to the PEGASYS Medication Guide for storage information about PEGASYS injection.

### General information about the safe and effective use of RIBASPHERE

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

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

### What are the ingredients in RIBASPHERE?

Active Ingredient: ribavirin

Inactive Ingredients: microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, NF, Povidone K 29-33, USP, magnesium stearate, NF, purified water, USP. 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.

Rx Only

Manufactured by  
**DSM PHARMACEUTICALS, INC.**  
Greenville, NC 27834  
for

**THREE RIVERS PHARMACEUTICALS, LLC**  
Cranberry Township, PA 16066

002482

<sup>1</sup> PEGASYS® is a registered trademark of Hoffmann-La Roche

Issued: 09/05

Printed in USA

Copyright © 2005 by Three Rivers Pharmaceuticals, LLC. All rights reserved.