

MEDICATION GUIDE

RIBASPHERE® (Rib-a-sphere)
(ribavirin capsules)

Rx Only

Read this Medication Guide before you start taking RIBASPHERE® (ribavirin capsules), and each time you get a refill. 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 (ribavirin capsules)?

1. **Do Not take RIBASPHERE (ribavirin capsules) alone to treat chronic hepatitis C infection.** RIBASPHERE (ribavirin capsules) should be used in combination with **either interferon alfa-2b (Intron® A¹) or peginterferon alfa-2b (Pegintron®²)** to treat chronic hepatitis C infection.
2. **RIBASPHERE (ribavirin capsules) may cause a significant drop in your red blood cell count and cause anemia in some cases. Anemia has been associated with worsening of Heart Problems, and in rare cases can cause a Heart Attack and Death.** Tell your health care provider if you have ever had any heart problems. RIBASPHERE (ribavirin capsules) may not be right for you. **Seek medical attention right away if you experience chest pain.**
3. **RIBASPHERE (ribavirin capsules) may cause Birth Defects or the Death of your unborn baby. Do Not Take RIBASPHERE (ribavirin capsules) if you or your sexual partner is pregnant or plan to become pregnant. Do Not become Pregnant within 6 months after discontinuing RIBASPHERE (ribavirin capsules) therapy.** You must use 2 forms of birth control when you take RIBASPHERE (ribavirin capsules) and for the 6 months after treatment.

- Females must have a pregnancy test before starting RIBASPHERE (ribavirin capsules), every month while taking RIBASPHERE (ribavirin capsules), and every month for the 6 months after the last dose of RIBASPHERE (ribavirin capsules).

- **If you or your female sexual partner becomes pregnant while taking RIBASPHERE (ribavirin capsules) or within 6 months after you stop taking RIBASPHERE (ribavirin capsules), tell your health care provider right away. You or your health care 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 (ribavirin capsules) while she is pregnant.**

What is RIBASPHERE (ribavirin capsules)?

RIBASPHERE (ribavirin capsules) is a medicine used with either interferon alfa-2b or peginterferon alfa-2b to treat chronic (lasting a long time) hepatitis C infection in people 3 years and older with liver disease.

It is not known if RIBASPHERE (ribavirin capsules) use for longer than 1 year is safe and will work.

It is not known if RIBASPHERE (ribavirin capsules) use in children younger than 3 years old is safe and will work.

Who should not take RIBASPHERE (ribavirin capsules)?

See “**What is the most important information I should know about RIBASPHERE (ribavirin capsules)?**”

Do not take RIBASPHERE (ribavirin capsules) if you have:

- or ever had serious allergic reactions to the ingredients in RIBASPHERE (ribavirin capsules). See the end of this Medication Guide for a complete list of ingredients.

- certain types of hepatitis (autoimmune hepatitis).

- certain blood disorders (hemoglobinopathies).

- severe kidney disease.

- taken or currently take didanosine (VIDEX®³).

Talk to your health care provider before taking RIBASPHERE (ribavirin capsules) if you have any of these conditions.

What should I tell my health care provider before taking RIBASPHERE (ribavirin capsules)?

Before you take RIBASPHERE (ribavirin capsules), tell your health care provider if you have or ever had:

- treatment for hepatitis C that did not work for you.

- breathing problems. RIBASPHERE (ribavirin capsules) may cause or worsen breathing problems you already have.

- vision problems. RIBASPHERE (ribavirin capsules) may cause eye problems or worsen eye problems you already have. You should have an eye exam before you start treatment with RIBASPHERE (ribavirin capsules).

- certain blood disorders such as anemia (low red blood cell count).

- high blood pressure, heart problems, or have had a heart attack. Your health care provider should check your blood and heart before you start treatment with RIBASPHERE (ribavirin capsules).

- thyroid problems.

- liver problems other than hepatitis C infection

- human immunodeficiency virus (HIV) or any immunity problems

- mental health problems, including depression or thoughts of suicide

- kidney problems

- an organ transplant

- diabetes. RIBASPHERE (ribavirin capsules) may make your diabetes worse or harder to treat

- any other medical condition

- are breastfeeding. It is not known if RIBASPHERE (ribavirin capsules) passes into your breast milk. You and your health care provider should decide if you will take RIBASPHERE (ribavirin capsules) or breastfeed.

Tell your health care provider about all the medicines you take, including prescription medicines, vitamins, and herbal supplements. RIBASPHERE (ribavirin capsules) may affect the way other medicines work.

Especially tell your health care provider if you take didanosine (VIDEX®³) or azathioprine (Imuran®⁴ and Azasan®⁵).

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

How should I take RIBASPHERE (ribavirin capsules)?

- Take RIBASPHERE (ribavirin capsules) exactly as your health care provider tells you. Your health care provider will tell you how much RIBASPHERE (ribavirin capsules) to take and when to take it.

- Take RIBASPHERE (ribavirin capsules) with food.

- Take **RIBASPHERE capsules** whole. Do not open, break, or crush **RIBASPHERE capsules** before swallowing. If you cannot swallow **RIBASPHERE capsules** whole, tell your health care provider.

- If you miss a dose of RIBASPHERE (ribavirin capsules), 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 health care provider.

- If you take too much RIBASPHERE (ribavirin capsules), call your health care provider or Poison Control Center at 1-800-222-1222, or go to the nearest hospital emergency room right away.

What are the possible side effects of RIBASPHERE (ribavirin capsules)?

RIBASPHERE (ribavirin capsules) may cause serious side effects, including:

See “**What is the most important information I should know about RIBASPHERE (ribavirin capsules)?**”

- **Swelling and irritation of your pancreas (pancreatitis).** You may have stomach pain, nausea, vomiting, or diarrhea.

- **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.

- **Dental problems.** Your mouth may be very dry, which can lead to problems with your teeth and gums.

- **Severe depression**

- **Suicidal thoughts and attempts.** Adults and children who take RIBASPHERE (ribavirin capsules), especially teenagers, are more likely to have suicidal thoughts or attempt to hurt themselves while taking RIBASPHERE (ribavirin capsules). Call your health care provider right away or go to the nearest hospital emergency room if you have new or worse depression or thoughts about suicide or dying.

- **Severe blood disorders.** An increased risk when used in combination with pegylated alpha interferons and azathioprine.

- **Growth problems in children.** Weight loss and slowed growth are common in children during combination treatment with peginterferon alfa-2b (Pegintron®²) or interferon alfa-2b (Intron® A¹). Most children will go through a growth spurt and gain weight after treatment stops. Some children may not reach the height that they were expected to have before treatment. Talk to your health care provider if you are concerned about your child’s growth during treatment with RIBASPHERE and peginterferon alfa-2b (Pegintron®²) or with RIBASPHERE and interferon alfa-2b (Intron® A¹).

Tell your health care provider right away if you have any side effect that bothers you or that does not go away.

The most common side effects of RIBASPHERE (ribavirin capsules) include:

- flu-like symptoms - feeling tired, headache, shaking along with high temperature (fever), nausea, and muscle aches.

- mood changes, feeling irritable.

The most common side effects of RIBASPHERE (ribavirin capsules) in children include:

- a decrease in the blood cells that fight infection (neutropenia).

- a decrease in appetite.

- stomach pain and vomiting.

Tell your health care provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of RIBASPHERE (ribavirin capsules). For more information ask your health care provider or pharmacist.

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

How should I store RIBASPHERE (ribavirin capsules)?

Store **RIBASPHERE (ribavirin capsules)** between 59° - 86°F (15° - 30°C).

Keep RIBASPHERE (ribavirin capsules) and all medicines out of the reach of children.

GENERAL INFORMATION ABOUT THE SAFE AND EFFECTIVE USE OF RIBASPHERE (RIBAVIRIN CAPSULES).

It is not known if treatment with RIBASPHERE (ribavirin capsules) will cure hepatitis C virus infections or prevent cirrhosis, liver failure, or liver cancer that can be caused by hepatitis C virus infections. It is not known if taking RIBASPHERE (ribavirin capsules) will prevent you from infecting another person with the hepatitis C virus.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use RIBASPHERE (ribavirin capsules) for a condition for which it was not prescribed. Do not give RIBASPHERE (ribavirin capsules) 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 RIBASPHERE (ribavirin capsules). If you would like more information, talk with your health care provider. You can ask your pharmacist or health care provider for information about RIBASPHERE (ribavirin capsules) that is written for health professionals.

What are the ingredients in RIBASPHERE (ribavirin capsules)?

Active ingredients: ribavirin

RIBASPHERE (ribavirin capsules)

Inactive ingredients: croscarmellose sodium, lactose monohydrate, microcrystalline cellulose, and povidone. The capsule shell consists of gelatin and titanium dioxide. The capsule is printed with edible green pharmaceutical ink which is made of butyl alcohol, NF, Yellow Iron Oxide, dehydrated alcohol, USP, FD&C Blue #2 Aluminum Lake, isopropyl alcohol, USP, propylene glycol, USP, Shellac, NF, strong ammonia solution, NF, and titanium dioxide.

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

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