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Ribavirin

pronounced as (rye ba vye' rin)

IMPORTANT WARNING:

Ribavirin will not treat hepatitis C (a virus that infects the liver and may cause severe liver damage or liver cancer) unless it is taken with another medication. Your doctor will prescribe another medication to take with ribavirin if you have hepatitis C. Take both medications exactly as directed.

Ribavirin may cause anemia (condition in which there is a decrease in the number of red blood cells) that can worsen any heart problems you have and can cause you to have a heart attack that can be life-threatening. Tell your doctor if you have ever had a heart attack and if you have or have ever had high blood pressure, breathing problems, any condition that affects your blood such as sickle cell anemia (inherited condition in which the red blood cells are abnormally shaped and cannot bring oxygen to all parts of the body) or thalassemia (Mediterranean anemia; a condition in which the red blood cells do not contain enough of the substance needed to carry oxygen), bleeding in the stomach or intestines, or heart disease. If you experience any of the following symptoms, call your doctor immediately: excessive tiredness, pale skin, headache, dizziness, confusion, fast heartbeat, weakness, shortness of breath, or chest pain.

Keep all appointments with your doctor and the laboratory. Your doctor will order blood tests before you start taking ribavirin and often during your treatment.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with ribavirin and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm> [<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>]) to obtain the Medication Guide.

Talk to your doctor about the risks of taking ribavirin.

For female patients:

Do not take ribavirin if you are pregnant or plan to become pregnant. You should not start taking ribavirin until a pregnancy test has shown that you are not pregnant. You must use two forms of

birth control and be tested for pregnancy every month during your treatment and for 6 months afterward. Call your doctor immediately if you become pregnant during this time. Ribavirin may cause harm or death to the fetus.

For male patients:

Do not take ribavirin if your partner is pregnant or plans to become pregnant. If you have a partner who can become pregnant, you should not start taking ribavirin until a pregnancy test shows that she is not pregnant. You must use two forms of birth control, including a condom with spermicide during your treatment and for 6 months afterward. Your partner must be tested for pregnancy every month during this time. Call your doctor immediately if your partner becomes pregnant. Ribavirin may cause harm or death to the fetus.

Why is this medication prescribed?

Ribavirin is used with an interferon medication such as peginterferon alfa-2a [Pegasys] or peginterferon alpha-2b [PEG-Intron] to treat hepatitis C in people who have not been treated with an interferon before. Ribavirin is in a class of antiviral medications called nucleoside analogues. It works by stopping the virus that causes hepatitis C from spreading inside the body. It is not known if treatment that includes ribavirin and another medication cures hepatitis C infection, prevents liver damage that may be caused by hepatitis C, or prevents the spread of hepatitis C to other people.

How should this medicine be used?

Ribavirin comes as a tablet, a capsule and an oral solution (liquid) to take by mouth. It is usually taken with food twice a day, in the morning and the evening, for 24 to 48 weeks or longer. Take ribavirin at around the same times every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take ribavirin exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Swallow the capsules whole; do not split, chew, or crush them.

Shake the liquid well before each use to mix the medication evenly. Be sure to wash the measuring spoon or cup after use each time you measure the liquid.

Your doctor may decrease your dose or tell you to stop taking ribavirin if you develop side effects of the medication or if certain laboratory tests show that your condition has not improved. Call your doctor if you are bothered by side effects of ribavirin. Do not decrease your dose or stop taking ribavirin unless your doctor tells you that you should.

Other uses for this medicine

Ribavirin is also sometimes used to treat viral hemorrhagic fevers (viruses that can cause bleeding inside and outside of the body, problems with many organs, and death). In the event of biological warfare, ribavirin may be used to treat viral hemorrhagic fever that has been spread deliberately.

Ribavirin is also sometimes used to treat severe acute respiratory syndrome (SARS; a virus that may cause breathing problems, pneumonia, and death). Talk to your doctor about the possible risks of using this drug for your condition.

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking ribavirin,

- tell your doctor and pharmacist if you are allergic to ribavirin, any other medications, or any of the ingredients in ribavirin tablets, capsules, or oral solution. Ask your pharmacist or check the Medication Guide for a list of the ingredients.
- tell your doctor if you are taking didanosine (Videx). Your doctor will probably tell you not to take ribavirin if you are taking this medication.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: azathioprine (Azasan, Imuran); medications for anxiety, depression, or other mental illness; nucleoside reverse transcriptase inhibitors (NRTIs) for human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS) such as abacavir (Ziagen, in Atripla, in Trizivir), emtricitabine (Emtriva, in Atripla, in Truvada), lamivudine (EpiVir, in Combivir, in Epzicom), stavudine (Zerit), tenofovir (Viread, in Atripla, in Truvada), and zidovudine (Retrovir, in Combivir, in Trizivir); and medications that suppress the immune system such as cancer chemotherapy, cyclosporine (Neoral, Sandimmune), sirolimus (Rapamune), and tacrolimus (Prograf). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you have kidney disease, liver failure, or autoimmune hepatitis (swelling of the liver that occurs when the immune system attacks the liver). Your doctor may tell you not to take ribavirin.
- tell your doctor if you drink or have ever drunk large amounts of alcohol, if you use or have ever used street drugs, if you have ever thought about killing yourself or planned or tried to do so, and if you have ever had a liver transplant or other organ transplant. Also tell your doctor if you have or have ever had a mental illness such as depression, anxiety, or psychosis (loss of contact with reality); cancer; HIV or AIDS; diabetes; sarcoidosis (a condition in which abnormal tissue grows in parts of the body such as the lungs); Gilbert's syndrome (a mild liver condition that may cause yellowing of the skin or eyes); gout (a type of arthritis caused by crystals deposited in the joints); any type of liver disease other than hepatitis C; or thyroid, pancreas, eye, or lung disease.
- tell your doctor if you are breast-feeding.
- you should know that ribavirin may make you drowsy, dizzy, or confused. Do not drive a car or operate machinery until you know how this medication affects you.
- do not drink alcoholic beverages while you are taking ribavirin. Alcohol can make your liver disease worse.
- you should know that your mouth may be very dry when you take this medication, which can lead to problems with your teeth and gums. Be sure to brush your teeth twice a day and have regular dental exams. If vomiting occurs, rinse your mouth out thoroughly.

What special dietary instructions should I follow?

Be sure to drink plenty of fluids while you are taking ribavirin.

What should I do if I forget a dose?

If you remember the missed dose that same day, take the medication right away. However, if you do not remember the missed dose until the next day, call your doctor to find out what to do. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Ribavirin may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- cough
- upset stomach
- vomiting
- diarrhea
- constipation
- heartburn
- loss of appetite
- weight loss
- changes in ability to taste food
- dry mouth
- difficulty concentrating
- difficulty falling asleep or staying asleep
- memory loss
- rash
- dry, irritated, or itchy skin
- sweating
- painful or irregular menstruation (period)
- muscle or bone pain
- hair loss

Some side effects can be serious. The following symptoms are uncommon, but if you experience any of them, or those listed in the IMPORTANT WARNING section, call your doctor immediately:

- hives
- swelling of the face, throat, tongue, lips, eyes, hands, feet, ankles, or lower legs
- hoarseness
- difficulty swallowing or breathing

- pain in the stomach or lower back
- bloody diarrhea
- bright red blood in stools
- black, tarry stools
- stomach bloating
- confusion
- dark-colored urine
- yellowing of the skin or eyes
- unusual bleeding or bruising
- vision changes
- fever, chills, and other signs of infection
- depression
- thinking about hurting or killing yourself
- mood changes
- excessive worry
- irritability
- starting to use street drugs or alcohol again if you used these substances in the past
- intolerance to cold

Ribavirin may slow growth and weight gain in children. Talk to your child's doctor about the risks of giving this medication to your child.

Ribavirin may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store ribavirin tablets and capsules at room temperature and away from excess heat and moisture (not in the bathroom). Store ribavirin oral solution in the refrigerator or at room temperature.

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your

pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>]. If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

What other information should I know?

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Copegus[®]
- Moderiba[®]
- Rebetol[®]
- Ribasphere[®]
- Virazole[®]

Other names

- tribavirin
- RTCA

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