

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PART III: PATIENT MEDICATION INFORMATION

PrMODERIBA™

ribavirin, tablets

Read this carefully before you start taking MODERIBA™ (ribavirin) and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about MODERIBA™.

What is MODERIBA™ used for?

MODERIBA™ is used for the treatment of chronic (lasting a long time) hepatitis C virus (HCV) in adults in combination with other medications.

When you have hepatitis C, you have the virus in your blood and in your liver. Chronic hepatitis C can lead to cirrhosis (liver scarring), liver failure and even liver cancer later in life.

Also read the patient information for the other medications prescribed by your doctor for the treatment of chronic hepatitis C, before taking MODERIBA™.

How does MODERIBA™ work?

MODERIBA™ when taken with other medications may cure chronic hepatitis C infection in the majority of patients. Cure means the hepatitis C virus is cleared from your blood (remains at an undetectable level) when measured three months after finishing all treatment.

Curing chronic hepatitis C can help reduce the risk of illness and death associated to liver disease.

Does MODERIBA™ reduce the risk of passing HCV to others?

Hepatitis C can be passed to other individuals through contact with infected blood. Talk with your healthcare provider about ways to prevent spreading the hepatitis C virus.

What are the ingredients in MODERIBA™?

Medicinal ingredients: ribavirin

Non-medicinal ingredients:

MODERIBA™ 200 mg tablets also contain carnauba wax, croscarmellose sodium, indigo carmine aluminum lake lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, talc, titanium dioxide.

MODERIBA™ 400 mg tablets also contain brilliant blue FCF aluminum lake, carnauba wax, croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, talc, titanium dioxide.

MODERIBA™ 600 mg tablets also contain brilliant blue FCF aluminum lake, carnauba wax, croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, talc, titanium dioxide.

MODERIBA™ comes in the following dosage forms:

MODERIBA™ tablets come in three strengths: 200 mg, 400 mg or 600 mg of ribavirin.

Do not use MODERIBA™ if:

- **you ever had an allergic reaction to ribavirin or any component of MODERIBA™ (see Non-medicinal ingredients).**
- **you are pregnant or planning to become pregnant, if you are male and have a female partner who is pregnant or is planning to become pregnant (see Serious Warnings and Precautions and Pregnancy).**
- **you have anemia. MODERIBA™ may cause your red blood cell count to decrease (anemia). This can be dangerous, especially if you have heart or breathing problems. This may cause a worsening of heart (cardiovascular) or circulatory problems.**
- **you have hemoglobinopathies (blood disorders) including thalassemia or sickle cell anemia.**
- **you are taking didanosine. Fatal hepatic failure (liver failure resulting in death), peripheral neuropathy (tingling, pain, numbness or weakness in the arms or legs), pancreatitis (inflammation of the pancreas), symptomatic hyperlactatemia/lactic acidosis (a build-up of lactic acid in the body, leading to the blood becoming acidic) have been reported in patients receiving both didanosine and ribavirin.**

Serious Warnings and Precautions

- **MODERIBA™ (ribavirin) taken alone is not effective treatment for chronic hepatitis C infection.**
- **MODERIBA™ use is associated with hemolytic anemia (loss of red blood cells) which can worsen any heart problems you have and may lead to heart attack or death. If you have heart disease you should not take MODERIBA™.**
- **MODERIBA™ may cause birth defects or death of your unborn baby. Do not take MODERIBA™ if you are pregnant. Male partners must not take MODERIBA™ if their female partners are pregnant. Females and female partners of males taking MODERIBA™, must avoid pregnancy during MODERIBA™ therapy and for 6 months after stopping MODERIBA™.**

Pregnancy:

If you are a **woman** of childbearing age who is taking MODERIBA™, you must have a negative pregnancy test before treatment, each month during therapy and for the six months after treatment is stopped. You must use two methods of effective birth control during the time you are taking the treatment and for six months after stopping treatment. This can be discussed with your doctor.

If you are a **man** who is taking MODERIBA™ and your female partner is not pregnant but is of childbearing age, she must be tested for pregnancy each month during treatment and for the six months after treatment has stopped. You or your partner must use two methods of effective birth control during the time you are taking the treatment and for six months after stopping treatment. This can be discussed with your doctor.

If you or your female partner becomes pregnant while taking MODERIBA™ in combination with other medicines or within six months after you stop taking these medicines, tell your healthcare provider.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take MODERIBA™. Talk about any health conditions or problems you may have, including if you:

- have been withdrawn from previous therapy for hepatitis C because of anemia or low blood count.
- are co-infected with HIV (the virus that causes AIDS) or the hepatitis B virus (HBV). Tell your doctor if you are being treated for HIV or HBV.
- have liver problems other than hepatitis C infection.

- have any other medical condition.
- have a heart problem or a history of heart disease. In this case your doctor will monitor you carefully.
- have a problem with your kidneys. Your doctor may decide that MODERIBA™ treatment should be decreased or stopped.
- have had an organ transplant (such as liver or kidney) and are taking medicine that keeps your body from rejecting your transplant (suppresses your immune system). Or you have one planned in the near future.
- are pregnant, planning to become pregnant, breastfeeding or plan to breastfeed. It is not known if MODERIBA™ passes into your breast milk. You and your healthcare provider should decide if you will take MODERIBA™ or breastfeed. You should not do both.

Other warnings you should know about:

MODERIBA™ is administered with other medications. The Patient Medication Information(s) of medications used in combination with ribavirin should be consulted before starting treatment with MODERIBA™.

It is not known if taking MODERIBA™ with other medications is safe and effective in children under 18 years of age.

Your doctor may do blood tests before you start your treatment and regularly during your treatment. These blood tests are done to help your doctor to check if the treatment is working for you and to check for side effects.

MODERIBA™ 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.

Let your doctor know if you are taking didanosine. Lactic acidosis (a build-up of lactic acid) in body, leading to the blood becoming acidic) and worsening liver function are side effects associated with didanosine.

When ribavirin is taken with azathioprine, pancytopenia (decreased red blood cells, white blood cells and platelets) and bone marrow suppression (tissue in the bones that makes these blood cells) have been seen. This was reversible when these treatments were stopped.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

For detailed information on drugs interactions refer to the Patient Medication Information(s) of medications used in combination with ribavirin.

Drugs that may interact with MODERIBA™ include: didanosine (e.g., Videx EC®), stavudine (e.g., Zerit®), zidovudine (e.g., Retrovir®), azathioprine (e.g., Imuran®), lamivudine (e.g., Heptovir®).

Know all the medicines that you take. Keep a list of them with you to show healthcare provider and pharmacist when you get a new medicine.

While MODERIBA™ when taken with other medications may cure chronic hepatitis C infection, it does not protect you from HCV reinfection. Talk with your healthcare provider about ways to prevent reinfection with the hepatitis C virus.

How to take MODERIBA™

- Take MODERIBA™ exactly as your healthcare provider tells you to take it. Do not change your dose unless your healthcare provider tells you to.
- Do not stop taking MODERIBA™ to ensure that your medicine continues to work against the virus, unless your doctor tells you to. If you think there is a reason to stop taking MODERIBA™, talk to your healthcare provider before doing so.
- Take MODERIBA™ at about the same time every day.
- Take MODERIBA™ tablets with food. The type of food is not important.
- Swallow MODERIBA™ tablets whole, with water as required. Do not chew, break, or crush MODERIBA™ tablets.

Usual dose:

- Your healthcare provider will determine the correct dose of MODERIBA™ tablets based on your weight and the genotype of the disease you have.
- Your healthcare provider will tell you exactly how long you need to take MODERIBA™ combination therapy.

Overdose:

If you think you have taken too much MODERIBA™ contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

- If you miss a dose of MODERIBA™ tablets and remember **within 6 hours**, it should be taken as soon as possible. If more than 6 hours has passed since MODERIBA™ is usually taken, the missed dose should NOT be taken and you should take the next dose as

per the usual dosing schedule. Do not take two doses at the same time.

What are possible side effects from using MODERIBA™?

These are not all the possible side effects you may feel when taking MODERIBA™. If you experience any side effects not listed here, contact your healthcare professional. Please also see **Other warnings you should know about.**

Side effects of MODERIBA™ when taken with other medications:

- feeling tired (fatigue)
- itching
- feeling weak or lack of energy (asthenia)
- low red blood cell count (anemia)
- nausea
- trouble sleeping

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM				
Symptoms/Effect*		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Very common	Low red blood cell count (anemia) with symptoms such as weakness, fatigue, shortness of breath, pale skin, dizziness		✓	
	Low blood platelet count (thrombocytopenia) when used with azathioprine, with symptoms such as bruising or increased bleeding		✓	
	Low white blood cell count (neutropenia) when used with azathioprine, with symptoms such as increased infection		✓	

*These side effects are commonly associated with peginterferon alfa and ribavirin therapy.

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at [MedEffect](http://www.healthcanada.gc.ca/medeffect) (www.healthcanada.gc.ca/medeffect);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator 0701D
Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](http://www.healthcanada.gc.ca/medeffect) (www.healthcanada.gc.ca/medeffect).

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store between 15 and 30°C. Keep the bottle tightly closed in order to protect from moisture.

Keep MODERIBA™ out of the reach and sight of children.

If you want more information about MODERIBA™:

- Talk to your healthcare professional
- Find the most recent version of the full Product Monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the [Health Canada website](http://www.healthcanada.gc.ca) (www.healthcanada.gc.ca); the manufacturer's website abbvie.ca, or by calling 1-888-704-8271.

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