



**Package Leaflet:**  
**Information for the patient**  
**Ribavirin 200 mg film-coated tablets**  
**Ribavirin 400 mg film-coated tablets**  
ribavirin

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

1. What Ribavirin is and what it is used for
2. What you need to know before you take Ribavirin
3. How to take Ribavirin
4. Possible side effects
5. How to store Ribavirin
6. Contents of the pack and other information

**1. What Ribavirin is and what it is used for**

Ribavirin, which is the antiviral active substance of Ribavirin, inhibits the multiplication of many types of viruses, including the hepatitis C viruses (which can cause an infection of the liver called hepatitis C).

Ribavirin is used in combination with other medicines to treat certain chronic forms of hepatitis C.

Ribavirin should only be used in combination with other medicines to treat hepatitis C. It should not be taken alone.

Refer also to the package leaflets of the other medicines that are used in combination with Ribavirin.

**2. What you need to know before you take Ribavirin**

**Do not take Ribavirin:**

- if you are allergic to ribavirin or to any of the other ingredients of this medicine (listed in section 6).
- if you are pregnant or breast-feeding (see section "Pregnancy and breast-feeding").
- if you have had a heart attack or have suffered from any other severe heart disease in the previous six months.
- if you have a blood disorder such as sickle cell anaemia or thalassaemia (weakening and destruction of red blood cells).

Refer also to the package leaflets of the other medicines that are used in combination with Ribavirin. Do not take Ribavirin in combination with medicines called interferons or pegylated interferons if you have an advanced liver disease (e.g. your skin has become yellow and you have excess fluid in your abdomen).

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Ribavirin

- If you are a woman of child-bearing age (see section "Pregnancy and breast-feeding").
- If you are a man and your female partner is of childbearing age (see section "Pregnancy and breast-feeding").
- If you have a heart problem. In this case you will need to be monitored carefully. A heart recording (ECG or electrocardiogram) is recommended prior to and during treatment.
- If you develop a heart problem along with intense fatigue. This may be due to anaemia caused by Ribavirin.
- If you have ever had anaemia (the risk of developing anaemia is higher in women compared to men, in general).
- If you have a problem with your kidneys. Ribavirin treatment may need to be decreased.
- If you have had an organ transplant (such as liver or kidney) or have one planned in the near future.
- If you develop symptoms of an allergic reaction such as difficulty in breathing, wheezing, sudden swelling of the skin and mucous membranes, itching or rashes. Ribavirin treatment must be stopped immediately and you should seek medical help immediately.
- If you have ever had depression or develop symptoms associated with depression (e.g. feelings of sadness, dejection, etc) while on treatment with Ribavirin (see section 4).
- If you are an adult who has or had a history of substance abuse (e.g. alcohol or drugs).
- If you are under the age of 18. The efficacy and safety of Ribavirin in combination with peginterferon alfa-2a or interferon alfa-2a have not been sufficiently evaluated in patients under the age of 18 years.
- If you are co-infected with HIV and are being treated with any anti HIV medicinal products.
- If you have been withdrawn from previous therapy for hepatitis C because of anaemia or low blood count.

Before treatment with Ribavirin, kidney function must be tested in all patients. Your doctor must also test your blood before starting treatment with Ribavirin. The blood tests should be repeated after 2 and 4 weeks of treatment, and thereafter as frequently as your doctor thinks is necessary.

If you are a woman of childbearing age, you must have a pregnancy test before starting treatment with Ribavirin, every month during treatment and during the 9 months after treatment (see section "Pregnancy and breast-feeding").

The following severe side effects are associated in particular with Ribavirin use in combination with interferon alfa-2a or peginterferon alfa-2a, please refer to the package leaflet of these medicinal products for more detailed information on these safety issues:

- Psychiatric and central nervous system effects (such as depression, suicidal thoughts, attempted suicide and aggressive behavior, etc.). Be sure to seek emergency care if you notice that you are becoming depressed or have suicidal thoughts or change in your behaviour. You may want to consider asking a family member or close friend to help you stay alert to signs of depression or changes in your behaviour
- Severe ocular disorder
- Dental and periodontal disorders: Dental and gum disorders have been reported in patients receiving Ribavirin and peginterferon alfa-2a combination therapy. You should brush your teeth thoroughly twice daily and have regular dental examinations. In addition some patients may experience vomiting. If you have this reaction, be sure to rinse your mouth thoroughly afterwards.
- Growth inhibition in children and adolescents that may be irreversible in some patients

**Other medicines and Ribavirin**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Patients who also have HIV infection: Tell your doctor if you are being treated for HIV.

Lactic acidosis (a build up of lactic acid in the body, leading to the blood becoming acidic) and worsening liver function are side effects associated with HAART (Highly Active Anti-Retroviral Therapy), an HIV treatment regimen. If you are receiving HAART, the addition of Ribavirin to peginterferon alfa-2a or interferon alfa-2a may increase your risk of lactic acidosis or liver failure. Your doctor will monitor you for signs and symptoms of these conditions.

If you take zidovudine or stavudine, because you are HIV positive or suffering from AIDS it is possible that Ribavirin can decrease the effect of these medicines. Therefore your blood will be checked regularly to make sure the HIV infection is not getting worse. If it does get worse, your doctor may decide to stop your treatment with Ribavirin. In addition, patients receiving zidovudine in combination with Ribavirin and alfa interferons are at increased risk of developing anaemia.

Co-administration of Ribavirin and didanosine, (which is a treatment for HIV) is not recommended. Certain side effects of didanosine (e.g. liver problems, tingling and painful arms and/or feet, pancreatitis) may occur more frequently.

Patients receiving azathioprine in combination with Ribavirin and peginterferon are at increased risk of developing severe blood disorders.

Refer also to the package leaflets of the other medicines that are used in combination with Ribavirin.

Ribavirin may remain in your body for up to 2 months, therefore you should check with your doctor or pharmacist before starting treatment with any of the other medicines mentioned in this leaflet.

**Ribavirin with food and drink**

Ribavirin film-coated tablets are normally taken at two times in the day with food (morning and evening) and should be swallowed whole.

**Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Ribavirin can be very harmful to the unborn child; it may cause birth defects. Therefore, if you are a **female patient**, it is very important to avoid becoming pregnant during treatment and during the 9 months after treatment. Ribavirin can damage the sperm and so harm the embryo (unborn child). Therefore, if you are a **male patient**, it is very important for your female partner to avoid becoming pregnant during your treatment and during the 6 months after treatment.

If you are a **woman** of childbearing age who is taking Ribavirin, you must have a negative pregnancy test before treatment, each month during therapy and for the 9 months after treatment is stopped. You must use an effective contraceptive during the time you are taking the treatment and for 9 months after stopping treatment. This can be discussed with your doctor. If your male partner is being treated with Ribavirin, please see the section "If you are a **man**".

If you are a **man** who is taking Ribavirin, do not have sex with a pregnant woman unless you use a condom. This will lessen the chance for ribavirin to be left in the woman's body. If your female partner is not pregnant now but is of childbearing age, she must be tested for pregnancy each month during treatment and for the 6 months after treatment has stopped. You or your partner must use an effective contraceptive during the time you are taking the treatment and for 6 months after stopping treatment. This can be discussed with your doctor. Please see "if you are a **woman**" if your female partner is treated with Ribavirin.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

It is not known whether Ribavirin is excreted in human milk. Women should not breast-feed while taking Ribavirin as this may harm the baby. If treatment with Ribavirin is necessary, breast-feeding should be stopped.

Refer also to the package leaflets of the other medicines that are used in combination with Ribavirin for the treatment of hepatitis C.

**Driving and using machines**

Ribavirin has very little effect on your ability to drive or use machines.

However, the other medicines you take with Ribavirin may have an effect. Check the package leaflets of the other medicines you are using in combination with Ribavirin.

**Ribavirin contains Sodium**

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium free'.

**3. How to take Ribavirin**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will decide the correct dose for you depending on your body weight, and type of virus and the medicine you take in combination with Ribavirin.

The recommended dose ranges between 800mg to 1400mg day depending on the other medicines you are using in combination with Ribavirin.

**For 200 mg:**

- 800 mg/day: Take 2 Ribavirin 200 mg tablets in the morning and 2 tablets in the evening
- 1000 mg/day: Take 2 Ribavirin 200 mg tablets in the morning and 3 tablets in the evening
- 1200 mg/day: Take 3 Ribavirin 200 mg tablets in the morning and 3 tablets in the evening
- 1400mg/day: Take 3 Ribavirin 200mg tablets in the morning and 4 tablets in the evening

**For 400 mg:**

The recommended dose ranges between 800 mg to 1400 mg/day depending on the other medicines you are using in combination with Ribavirin.

- 800 mg/day: Take 1 Ribavirin 400 mg tablet in the morning and 1 tablet in the evening
- 1000 mg/day: Patients are advised to take Ribavirin 200 mg tablets
- 1200 mg/day: Patients are advised to take Ribavirin 200 mg tablets
- 1400 mg/day: Patients are advised to take Ribavirin 200 mg tablets

In the case of combination therapy with other medicines please follow the dosing regimen recommended by your doctor and refer also to the package leaflets of the other medicines.

Swallow the tablets whole and take the tablets with food.

As ribavirin is teratogenic (may cause abnormalities in the unborn child), the tablets should be handled with care and should not be broken or crushed. If you accidentally touch damaged tablets, wash thoroughly with soap and water any part of your body which came in contact with the contents of the tablet. If any powder from the tablets gets in your eyes, rinse your eyes thoroughly with sterile water, or plain water if sterile water is not available.

The amount of time you have to continue taking Ribavirin film-coated tablets varies, depending on the type of virus you are infected with, which other medicine you are being treated with, on treatment response and whether you have been treated before. Please check with your doctor and follow the recommended duration of treatment.

If you are over the age of 65 you should consult your doctor before using Ribavirin.

If you have the impression that the effect of Ribavirin is too strong or too weak, talk to your doctor or pharmacist.

If side-effects occur during treatment, your doctor may adapt the dose or stop treatment.

Refer also to the package leaflets of the other medicines that are used in combination with Ribavirin.

**If you take more Ribavirin than you should**

Contact your doctor or pharmacist as soon as possible.

**If you forget to take Ribavirin**

Do not take a double dose to make up for a forgotten dose. If you miss a dose, take it as soon as you remember and take the next dose at the normal time.

**If you stop taking Ribavirin**

Only your doctor can decide when your treatment should be discontinued. Never stop the treatment yourself because the disease, for which you are being treated, can come back or get worse.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

During treatment, your doctor will take blood samples regularly to check for changes in your white blood cells (cells that fight infection), red blood cells (cells that carry oxygen), platelets (blood clotting cells), liver function or changes in other laboratory values.

Tell your doctor immediately if you notice any of the following side effects occur: severe chest pain; persistent cough; irregular heartbeat; trouble breathing; confusion; depression; severe stomach pain; blood in stools (or black, tarry stools); severe nosebleed; fever or chills; problems with your eyesight. These side effects can be serious and you may need urgent medical attention.





**Very common side effects with the combination of pegylated alfa interferon and ribavirin (may affect more than 1 in 10 people) are:**

Blood disorders: Anaemia (low red cell count), neutropenia (low white blood cell count)

Metabolic disorders: Loss of appetite

Psychiatric disorders: Feeling depressed (feeling low, feeling bad about yourself or feeling hopeless), inability to sleep

Nervous system disorders: Headache, difficulty concentrating and dizziness

Respiratory disorders: Cough, shortness of breath

Gastrointestinal disorders: Diarrhoea, nausea, abdominal pain

Skin disorders: Loss of hair, and skin reactions (including itching, dermatitis and dry skin).

Musculoskeletal disorders: Pain in joints and muscles

General disorders: Fever, weakness, tiredness, shaking, chills, pain, and irritability (getting easily upset)

**Common side effects with the combination of pegylated alfa interferon and ribavirin (may affect up to 1 in 10 people):**

Infections: Upper respiratory infection, bronchitis, fungal infection of the mouth and herpes (a common recurring viral infection affecting the lips, mouth)

Blood disorders: Low platelet count (affecting the clotting ability) and enlarged lymph glands.

Endocrine disorders: Overactive and underactive thyroid gland

Psychiatric disorders: Mood /emotion changes, anxiety, aggression, nervousness, decreased sexual desire

Nervous system disorders: Poor memory, fainting, decreased muscle strength, migraine, numbness, tingling, burning sensation, tremor, changes in the sense of taste, nightmares, sleepiness

Eye Disorders: Blurry vision, eye pain, eye inflammation and dry eyes.

Ear disorders: Sensation of room spinning, ear pain, ringing in ears

Cardiac disorders: Rapid heart rate, pulsation of the heart beats, swelling in the extremities.

Vascular disorders: Flushing, low blood pressure

Respiratory disorders: Shortness of breath with activity, nose bleeds, nose and throat inflammation, infections of the nose and sinuses (air-filled spaces found in the bones of the head and face), runny nose, sore throat

Gastrointestinal disorders: Vomiting, indigestion, difficulty swallowing, mouth ulceration, bleeding gums, inflammation of tongue and mouth, flatulence (excess amount of air or gases), constipation, dry mouth.

Skin disorders: Rash, increased sweating, psoriasis, hives, eczema, sensitivity to sunlight, night sweats

Musculoskeletal disorders: Back pain, joint inflammation, muscle weakness, bone pain, neck pain, muscle pain, muscle cramps

Reproductive system disorders: Impotence (inability to maintain an erection)

General disorders: Chest pain, flu-like illness, malaise (not feeling well), lethargy, hot flushes, thirst, weight decreased

**Uncommon side effects with the combination of pegylated alfa interferon and ribavirin (may affect up to 1 in 100 people):**

Infections: Lower respiratory tract infections, urinary tract infection, skin infections

Immune disorders: Sarcoidosis (areas of inflamed tissue occurring throughout the body), inflammation of the thyroid.

Endocrine disorders: Diabetes (high blood sugar)

Metabolic disorders: Dehydration

Psychiatric disorders: Thoughts of suicide, hallucinations (abnormal perceptions), anger

Nervous system disorder: Peripheral neuropathy (disorder of the nerves affecting the extremities)

Eye disorder: Bleeding in the retina (back of the eye)

Ear and labyrinth disorders: Hearing loss

Vascular disorder: High blood pressure

Respiratory disorder: Wheezing

Gastrointestinal disorders: Gastrointestinal bleeding, inflammation of the lips, inflammation of the gums

Liver disorders: Poor functioning of the liver

**Rare side effects with the combination of pegylated alfa interferon and ribavirin (may affect up to 1 in 1000 people):**

Infections: Infection of the heart, infection of the external ear

Blood disorders: Severe reduction in red blood cells, white blood cells and platelets

Immune system disorders: Severe allergic reaction, systemic lupus erythematosus (an illness where the body attacks its own cells), rheumatoid arthritis (an autoimmune disease)

Psychiatric disorders: Suicide, psychotic disorders (severe problems with personality and deterioration in normal social functioning).

Nervous system disorders: Coma (a deep prolonged unconsciousness), seizures, facial palsy

Eye disorders: Inflammation and swelling of the optic nerve, inflammation of the retina, ulceration of the cornea

Cardiac disorders: Heart attack, heart failure, heart pain, rapid heart rhythm, rhythm disorders or inflammation of the lining of the heart

Vascular disorders: Bleeding in the brain, vasculitis (inflammation of the blood vessels)

Respiratory disorders: Interstitial pneumonia (inflammation of the lungs with fatal outcome), blood clots in the lung

Gastrointestinal disorders: Stomach ulcer, inflammation of the pancreas

Liver disorders: Liver failure, bile duct inflammation, fatty liver

Musculoskeletal disorders: Inflammation of the muscles

Injury or poisoning: Substance overdose

**Very rare side effects with the combination of pegylated alfa interferon and ribavirin (may affect up to 1 in 10,000 people):**

Blood disorders: Aplastic anaemia (failure of the bone marrow to produce red blood cells, white blood cells and platelets).

Immune System disorders: Idiopathic (or thrombotic) thrombocytopenic purpura (increased bruising, bleeding, decreased platelets, anaemia and extreme weakness)

Eye disorders: Loss of vision

Nervous System disorders: Stroke

Skin disorders: Toxic epidermal necrolysis/ Stevens Johnson Syndrome/ erythema multiforme (a spectrum of rashes with varying degrees of severity which may be associated with blisters in the mouth, nose, eyes and other mucosal membranes), angioedema (swelling in the skin and mucosa)

**Side effects with unknown frequency:**

Blood disorders: Pure red cell aplasia (a severe form of anaemia where red blood cell production is decreased, or stopped); it can result in symptoms such as feeling very tired with no energy.

Immune System disorders: liver and kidney transplant rejections, Vogt Koyanagi Harada Syndrome –a rare disease characterised by loss of vision, hearing, and skin pigmentation.

Psychiatric disorders: mania (episodes of exaggerated elevation of mood) and bipolar disorders (episodes of exaggerated elevation of mood alternating with sadness or hopelessness).

Eye disorders: Rare form of retinal detachment with fluid in the retina

Digestive system disorders: Ischemic colitis (insufficient blood supply to the bowels), ulcerative colitis (inflammation of the large intestine that causes ulcers, resulting in diarrhoea), change in colour of the tongue

Musculoskeletal disorders: Serious muscle damage and pain.

Renal disorders: kidneys stop functioning adequately, other complaints that suggest kidney problems.

If you are infected with both viruses, HCV and HIV, and are receiving HAART (Highly Active Anti- Retroviral Therapy), the addition of ribavirin to peginterferon alfa-2a or interferon alfa-2a therapy may cause fatal liver failure, peripheral neuropathy (numbness, tingling or pain in hands or feet), pancreatitis (symptoms may include stomach pain, nausea and vomiting), lactic acidosis (a build up of lactic acid in the body, leading to the blood becoming acidic), influenza, pneumonia, affect lability (alterations in mood), apathy (lethargy), pharyngolaryngeal pain (pain in the back of your mouth and throat), cheilitis (dry and cracked lips), acquired lipodystrophy (increased amount of fat in upper back and neck) and chromaturia (change in colour of your urine) as side effects.

The side effects listed in this section were observed primarily when Ribavirin was used in combination with interferon-containing products.

When this medicine was used in combination with other medicines to treat hepatitis C (also called direct antiviral agents) in adult clinical studies, the most frequently reported side-effects associated with this medicine were anaemia (low red cell count), nausea, vomiting, tiredness, fatigue, insomnia (difficulty to sleep), cough, shortness of breath, itching and rash.

Refer also to the package leaflets of the other medicines that are used in combination with Ribavirin for information on the side effects for those products.

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Ribavirin**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label, carton, bottle after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**6. Contents of the pack and other information**

**What Ribavirin contains**

- The active substance is ribavirin. Each film-coated tablet contains 200 mg of ribavirin. Each film-coated tablet contains 400 mg of ribavirin.
- The other ingredients are  
*Tablet core:* Cellulose, microcrystalline, starch, pregelatinised (Maize starch), sodium starch glycolate (Type A), povidone (K-30), silica, colloidal anhydrous, magnesium stearate.  
*Film coating:*  
*200 mg:* HPMC 2910/ Hypromellose (15cP) (E464), titanium dioxide (E171), triacetin (E1518), iron oxide red (E172), iron oxide yellow (E172), ethyl cellulose (10cP) (E462).  
*400 mg:* Hypromellose 2910 (E464), titanium dioxide (E171), triacetin (E1518), iron oxide red (E172), iron oxide yellow (E172), talc (E533b).

**What Ribavirin looks like and contents of the pack**

Film-coated tablet.

*Ribavirin 200 mg:*  
Light pink colored, capsule shaped, film-coated tablets debossed with 'F' on one side and '10' on the other side.

*Ribavirin 400 mg:*  
Reddish brown colored, oval shaped, beveled biconvex, film-coated tablets debossed with 'F' on one side and '11' on the other side.

Ribavirin film-coated tablets are available in clear PVC - Aluminium foil blister pack and HDPE bottle packs with polypropylene closure.

*Pack sizes:*  
*Blister pack:* 14, 20, 28, 42, 56, 84, 112, 140 and 168 film-coated tablets  
*HDPE bottle pack:*  
*200 mg:* 28, 42, 56, 112, 168 and 500 film-coated tablets  
*400 mg:* 14, 28, 56, 84 and 500 film-coated tablets

Not all pack sizes may be marketed

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