

IBAVYR®

200mg, 400 mg, 600 mg ribavirin tablets

contains the active ingredient ribavirin

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about IBAVYR.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using IBAVYR against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may want to read it again.

What IBAVYR is used for

IBAVYR Tablets contain the active ingredient ribavirin. Ribavirin belongs to a group of medicines called antivirals.

IBAVYR is used in combination with other oral agents for the treatment of chronic hepatitis C (CHC). CHC is a viral infection of the liver. There are different types of the hepatitis C virus, referred to as genotypes. If this viral infection is not managed in some people, the liver becomes badly damaged and scarred. This is called cirrhosis. Cirrhosis can cause the liver to stop working. CHC may also be

associated with the development of hepatocellular carcinoma.

IBAVYR is not effective when used alone and must only be used in combination with other oral agents. For more information please refer to the respective Consumer Medicine Information of the other oral agent used during the treatment.

This medicine is available only with a doctor's prescription.

Before you take IBAVYR

When you must not take it

Do not take Ibvayr if you are allergic to:

- ribavirin, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description
- any other similar medicines

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take Ibvayr if:

- **you or your partner is pregnant or planning to become pregnant.**

IBAVYR may cause birth defects and/or death of an unborn baby. It is very important that you or

your partner avoid becoming pregnant during treatment and for 6 months after treatment. This is because IBAVYR Tablets can affect the sperm as well as the unborn child.

- **you are taking didanosine (a medicine used to treat patients with human immunodeficiency virus (HIV)).**
- **you have blood disorders including anaemia (low number of red blood cells), thalassaemia (Mediterranean anaemia) or sickle-cell anaemia**
- **the packaging is torn or shows signs of tampering.**
- **the expiry date (EXP) printed on the packs has passed. If you use it after the expiry date it may not work as well.**

If you are not sure whether you should start taking IBAVYR, talk to your doctor or pharmacist.

Before you start to take it

If you are or your partner is a woman of childbearing age, you or your partner must have a negative pregnancy test before treatment with IBAVYR Tablets starts.

You or your partner must also have a negative pregnancy test each month during treatment and for the 6 months after treatment is stopped. Two effective forms of contraception must be used, one by each partner, male and female, during treatment with IBAVYR Tablets and for the 6 months after treatment is completed. IBAVYR Tablets can cause harm to

the unborn child if a pregnant woman takes IBAVYR Tablets herself during pregnancy or has unprotected sex (sex without using a condom) with a man who is taking IBAVYR Tablets. IBAVYR Tablets can damage the sperm and the embryo (unborn child).

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Do not use IBAVYR Tablets if you are breastfeeding.

It is not known if IBAVYR passes into breast milk. Therefore to avoid any potential side effects in the nursing infant, nursing mothers should stop breast feeding when taking IBAVYR.

Do not give IBAVYR to children under 18 years of age.

Safety and effectiveness in children has not been established.

Tell your doctor if you have, or have ever had any of the following medical conditions before you start taking IBAVYR:

- heart problems such as congestive heart failure, irregular or very fast heartbeat, heart disease, or you have ever had a heart attack
- anaemia (a low number of red blood cells)
- kidney problems
- liver problems other than hepatitis C
- organ transplant
- HIV

Also refer to the respective Consumer Medicines Information of the other oral agent used during the treatment, for other things to be careful of when IBAVYR is taken in combination with other oral agents.

Taking other medicines

Tell your doctor if you are taking any other medicines including any that you have bought from a pharmacy, supermarket or health food shop.

You must not take IBAVYR if you are taking didanosine (a medicine used to treat HIV).

You must tell your doctor if you are taking:

- stavudine, zidovudine or lamivudine (medicines used to treat HIV), azathioprine (a medicine used to treat organ transplant patients), severe rheumatoid arthritis, systemic lupus erythematosus, dermatomyositis/polymyositis, autoimmune chronic active hepatitis, pemphigus vulgaris, polyarteritis nodosa, autoimmune haemolytic anaemia, chronic refractory idiopathic thrombocytopenic purpura

Some medicines may interfere with IBAVYR or may affect how well it works. You may need to use different amounts of your medicine or you may need to take different medicines. Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful of or avoid using while taking IBAVYR.

Ask your doctor or pharmacist if you are not sure about this list of medicines.

How to use IBAVYR

Take IBAVYR exactly as your doctor has directed.

Your doctor will tell you how many tablets to take each day.

Do not exceed the recommended dosage.

IBAVYR has a child resistant cap. To open cap, push cap downward and twist counter clockwise.

Please refer to illustration.



To close cap, place cap on bottle and turn clockwise.

How much to take

The usual dose of IBAVYR depends on your weight and genotype. This can range from 600 mg to 1200 mg daily, to be taken in two divided doses (morning and evening).

Routine blood tests will help your doctor to monitor your response to treatment.

Your doctor may adjust your dose during therapy according to your response.

How to take IBAVYR

IBAVYR should be taken with food.

Do not crush or chew the tablets.

IBAVYR 200mg and 600mg tablets should be swallowed whole with water. IBAVYR 400mg tablets are scored and can be split into two equal halves as necessary and should be swallowed with water.

When to take IBAVYR

Take IBAVYR during or immediately after a meal, at about the same times each day.

Taking IBAVYR at the same times every day will have the best effect and help you to remember to take your tablets.

How long to take IBAVYR

Do not stop taking IBAVYR unless your doctor tells you to stop.

Treatment is usually for at least 12 weeks and can go up to 24 weeks depending on your response.

If you become pregnant while using IBAVYR Tablets, you should immediately stop taking IBAVYR and tell your doctor. If you are male and your partner becomes

pregnant while you are taking IBAVYR, ask your partner to tell her doctor immediately.

If you forget to take it

If you miss a dose of IBAVYR do not take a double dose to make up for the tablet you missed.

Take the missed dose as soon as possible during the same day.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to use your medicine, ask your pharmacist for some helpful hints.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone number for Australia: 13 11 26, or New Zealand: 0800 764 766 [0800 POISON]) for advice, or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much IBAVYR, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep telephone numbers for these places handy.

While you are taking IBAVYR

Things you must do

Use IBAVYR Tablets exactly as your doctor has prescribed.

Tell all doctors, dentists and pharmacists who are treating you that you are taking IBAVYR.

Use contraception in order to avoid pregnancy.

Stop using IBAVYR Tablets if you become pregnant and immediately tell your doctor.

If you are male and your partner becomes pregnant while you are using IBAVYR, ask your partner to tell her doctor immediately.

Keep all your doctor's appointments so that your progress can be checked. Your doctor will carry out blood tests to monitor your response to treatment.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking IBAVYR.

Things you must not do

Do not stop taking IBAVYR or change the dose without first checking with your doctor.

Do not use it to treat any other complaints unless your doctor says to.

Do not give IBAVYR to anyone else, even if their symptoms seem similar to yours.

Do not let yourself run out of medicine over weekends or holiday periods.

Do not take any other medicines whether they require a prescription or not without first telling your doctor or pharmacist.

Things to be careful of

Be careful driving or operating machinery until you know how IBAVYR affects you.

If you become drowsy from the combination therapy, do not drive or use machinery.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking IBAVYR in combination with other oral agents.

The side effects listed below are possible side effects.

For more information please refer to the respective Consumer Medicine Information of the other oral agent used during the treatment.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- headache, fatigue, fever and chills
- weakness
- sleeplessness
- stomach pain, discomfort or constipation
- muscular ache and pain or joint pain
- agitation, irritability, mood swings, or disturbance in attention
- hair loss/change in hair texture, itching, rash or dry or redness of the skin
- sore throat, cough, shortness of breath
- back pain.

These are mild side effects of the medicine and are usually short-lived. If they continue or are severe, tell your doctor.

Tell your doctor as soon as possible if you notice any of the following:

- signs of anaemia such as tiredness, being short of breath and looking pale
- signs of liver decompensation such as a swollen abdomen lower back or side pain
- severe stomach pain

- fever or chills beginning after a few weeks of treatment
- persistent cough or shortness of breath
- depression
- confusion, trouble sleeping, thinking or concentrating

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- itchy rash,
- swelling of the face, lips or tongue,
- wheezing or troubled breathing or faintness.

These could be signs of a serious allergic reaction.

Other side effects not listed above may also occur in some patients. If you notice any other side effects, check with your doctor.

Check with your doctor as soon as possible if you have any problems while using the combination therapy, even if you do not think the problems are connected with the medicines.

After taking IBAVYR

Storage

Always keep this medicine in the bottle until it is time to take it.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store IBAVYR or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Keep bottle tightly closed.

Heat and dampness can destroy some medicines.

Keep IBAVYR where children cannot reach.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

Return any unused medicine to your pharmacist.

Product description

What it looks like

IBAVYR 200 mg tablets are white, capsule-shaped, coated tablet, debossed with "200" on one side and nothing on the other side.

IBAVYR 400 mg tablets are light pink, capsule-shaped coated tablets, debossed with "400" on one side and scored on the other side.

IBAVYR 600 mg tablets are white, capsule-shaped coated tablets, debossed with "600" on one side and nothing on the other side.

The tablets are packaged in HDPE bottles of 28 tablets with a child resistant closure.

Ingredients

Each IBAVYR tablet contains ribavirin as the active ingredient.

The tablets also contain the following inactive ingredients:

- Povidone
- Croscarmellose sodium
- Microcrystalline cellulose
- Crospovidone
- Silicon dioxide
- Magnesium stearate

The IBAVYR tablet coating contains:

- 400 mg: Opadry Orange 04F93451 (PI 109445)
- 200mg and 600 mg: Opadry White 03F180000 (PI 109444)

Supplier

In Australia and New Zealand:
 Clinect Pty Ltd
 120 - 132 Atlantic Drive
 Keysborough VIC 3173
 Australia

Free Call Australia:

1800 899 005

Free Call New Zealand:

0800 138 803

Australian Registration Number

AUST R 243632 - 200 mg tablets

AUST R 222627 - 400 mg tablets

AUST R 222628 - 600 mg tablets

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