

# COPEGUS<sup>®</sup> FILM-COATED TABLET

Ribavirin (200mg)

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## What Copegus is used for

Copegus contains the active ingredient *ribavirin*.

**Copegus is used to treat hepatitis C (a viral infection of the liver).** Copegus is not effective if used alone in the treatment of hepatitis C and must be used in combination with interferon alfa or peginterferon alfa injections. Refer also to the package leaflets of the other medicines that are used in combination with Copegus.

## How Copegus works

The medicine contained within Copegus, ribavirin, belongs to a group of medicines called antivirals. It works by inhibiting the multiplication of hepatitis C viruses.

If the viral infection is not managed effectively, the liver becomes badly damaged and scarring may occur in some people. This is known as cirrhosis.

## Before you use Copegus

### When you must not take it

Do not take Copegus if:

1. You are allergic to ribavirin or any of the ingredients listed at the end of this leaflet.  
Some of the symptoms of an allergic reaction may include:
  - shortness of breath
  - wheezing or difficulty in breathing
  - feeling faint
  - swelling of the face, lips, tongue or other parts of the body
  - rashes, itching, hives on the skin
2. You are pregnant, or plan to become pregnant, or your female partner is pregnant (if you are male)

There is an extremely high risk of causing harm to your unborn baby if you take Copegus during pregnancy. You must use effective contraception to avoid becoming pregnant while taking Copegus as well as 6 months after treatment.

3. You are breastfeeding or plan to start breastfeeding.

It is not known whether Copegus passes into breast milk.

Breastfeeding must stop before treatment of Copegus begins. Do not breastfeed while taking Copegus.

4. You have blood disorders (sickle-cell anemia, thalassemia).

5. The packaging is torn or shows signs of tampering.

6. The expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date has passed, it may not work as well.

Copegus combination therapy is not recommended if you have liver decompensation.

Inform your doctor if you have HIV and HCV infection with liver cirrhosis, as your doctor will decide whether Copegus still suits you.

If you are not sure if you should start taking Copegus, contact your doctor.

Do not give Copegus to children.

There is limited information on the use of Copegus in children less than 18 years of age.

### Before you start to take it

You must tell your doctor if:

1. You have any other health problems, especially the following:
  - severe heart problems or any previous heart condition
  - blood disorders including anemia (low numbers of red blood cells)
  - poor liver function
  - kidney disorders
  - if you have any transplanted organ
2. You have any allergies to any other medicines, foods, preservatives or dyes

If you have not told your doctor about any of the above, tell them before you start taking Copegus.

## Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription, from a pharmacy, supermarket or health food shop.

Some medicines may interfere with Copegus. These include:

- antacids, a group of medicines used to treat heartburn and indigestion
- stavudine, zidovudine and didanosine, medicines used to treat HIV/AIDS
- azathioprine, a medicine used to suppress the immune system

These medicines may be affected by Copegus, or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Copegus.

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

## How to take Copegus

### How much to take

Follow all directions given to you by your doctor or pharmacist carefully.

The usual dose of Copegus depends on your weight. This can range from 800mg to 1200mg and given in two divided doses (morning and evening).

Take Copegus exactly as your doctor has prescribed.

### When to take it

Copegus must always be taken during or after meals.

Copegus tablets should be taken at the same time every day.

Copegus tablet should be swallowed whole with a glass of water. Do not chew or crush the tablet.

This will give you the best effect and will help you remember when to take the tablets every day.

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If you are not sure when to take Copegus, ask your doctor.

## How long to take it

Copegus is usually taken for 24 to 72 weeks.

Ask your doctor if you are not sure how long to take Copegus for.

Continue taking your Copegus tablets until your doctor tells you to stop.

## If you forget to take it

Do not try to make up for missed doses by taking an extra dose.

This may increase the chances of getting unwanted side effects.

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

If you have missed several doses, please inform your doctor and follow the advice given to you.

## If you use too much (overdose)

You may need urgent medical attention. Contact your doctor or visit the nearest Accident & Emergency Department immediately (bring along the medication, carton and this leaflet if possible). Do this even if there are no signs of discomfort or poisoning.

## **While you are using Copegus**

### Things you must do

If you or your partner is of childbearing potential, routine pregnancy test must be performed monthly during treatment and for 6 months thereafter.

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

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you feel Copegus tablets are not helping your condition.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

Tell your doctor that you are taking Copegus if you are going for any laboratory tests.

### Things you must not do

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

Do not let yourself run out of medicine over the weekend or on holidays.

Do not give Copegus to anyone else even if their symptoms seem similar to yours or they have the same condition as you.

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

Do not take any other medicines whether they require prescriptions or not without first consulting with your doctor or a pharmacist.

### Things to be careful of

Do not drive or operate machinery until you know how Copegus affects you.

### **Side effects**

Copegus helps most people with chronic hepatitis C, but it may have unwanted side effects in a few people.

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

**The most serious possible side effect of Copegus is a reduction of red blood cells, this can worsen heart disease.**

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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

You may notice any of the following side effects if you are taking Copegus in combination with interferons.

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

- diarrhoea
- nausea (feeling like you want to vomit)
- fatigue (tiredness), weakness or weariness
- headache
- fatigue
- muscle ache
- flu-like symptoms
- weight loss
- stomach pain and indigestion
- temporary hair loss
- itchy skin rash or dry skin
- irritability (getting easily upset)
- insomnia (inability to sleep)
- aggressive behavior
- depression
- anxiety (a feeling of worry, nervousness or unease)

Tell your doctor immediately if you experience any of the following side effects:

- signs of anemia (tiredness, shortness of breath, dizziness, looking pale)
- severe chest pain
- persistent cough
- difficulty in breathing
- irregular heartbeat
- problems with eyesight (blurred or loss of vision) and hearing
- unusual bleeding or bruising
- severe depression or feeling suicidal
- thoughts of causing serious harm to others
- red or purple skin rash that spreads
- blisters, particularly on the mouth, nose or eyes
- fever or chills

These may be serious side effects. You may need urgent medical attention.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

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Ask your doctor or pharmacist if you don't understand anything in this list.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers → Reporting)

## Storage and disposal of Copegus

### Storage

Keep out of reach and sight of children. Do not store above 30°C. Store the medicine in its original container until you need to take it in order to protect it from moisture and light.

### Disposal

If your doctor tells you to stop taking Copegus, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

## Product Description

### What it looks like

Copegus comes as a 200mg film-coated tablet.

Copegus tablets are available in bottles of 42 and 168 tablets.

The 200mg tablet is a light pink oval shaped film-coated tablet. It is engraved with "RIB 200" on one side and "ROCHE" on the other.

## Ingredients

### Active ingredient

- each tablet contains 200 mg of ribavirin

### Inactive ingredients

The tablets also contain:

- pregelatinized starch
- sodium starch glycolate
- microcrystalline cellulose
- maize starch
- magnesium stearate

The tablets are coated with a film-coating which contains:

- hypromellsoe
- talc
- iron oxide, red
- iron oxide, yellow
- titanium dioxide
- ethylcellulose aqueous dispersion
- triacetin

### MAL number:

MAL08051760ACSZ

## Manufacturer

Made for F. Hoffmann-La Roche Ltd, Basel, Switzerland  
by Patheon Inc., Canada.

## Product Registration Holder

Roche (M) Sdn. Bhd.  
Level 21, The Pinnacle,  
Persiaran Lagoon, Bandar Sunway,  
47500 Subang Jaya,  
Selangor, Malaysia.

## Date of Revision

30/11/2015

## Serial Number

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