

## Consumer Medicine Information

# COPEGUS<sup>®</sup>

**Ribavirin**  
**200 mg film-coated tablets**

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### What is in this leaflet

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This leaflet answers some common questions about COPEGUS film-coated tablets.

It does not contain all 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 your taking COPEGUS against the benefits expected for you.

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

**Keep this leaflet with the medicine.**

You may need to read it again.

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### What COPEGUS is used for

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COPEGUS contains the active ingredient ribavirin.

COPEGUS belongs to a group of medicines called antivirals. These medicines work by preventing the activity of some viruses.

COPEGUS is used to treat chronic hepatitis C, which is an infection of the liver caused by a virus.

COPEGUS tablets are not effective when used on their own for hepatitis C and must be used in combination with PEGASYS<sup>®</sup> (peginterferon alfa-2a) or ROFERON-A<sup>®</sup> (interferon alfa-2a) injections. The combination of COPEGUS and PEGASYS or COPEGUS and ROFERON-A is more effective than treatment with PEGASYS or ROFERON-A alone.

People who get hepatitis C will usually carry the virus in their blood for the rest of their lives, unless successfully treated. Most patients will end up with some liver damage, but not all will feel sick in the earlier stages of the disease.

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 properly.

Cirrhosis can also be caused by caused by things other than viral infections such as long-term alcoholism.

It is not known if COPEGUS in combination with either ROFERON-A or PEGASYS can prevent liver failure or liver cancer that is caused by hepatitis infection.

**When you receive the combination therapy, you should also read the PEGASYS or ROFERON-A Consumer Medicine Information leaflet before use, depending on which medicine your doctor has prescribed.**

Your doctor, however, may have prescribed COPEGUS for another purpose.

**Ask your doctor if you have any questions about why COPEGUS has been prescribed for you.**

COPEGUS is not addictive.

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

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## **Before you take COPEGUS**

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### ***When you must not take COPEGUS***

**Do not take COPEGUS if:**

- 1. you are pregnant or your female partner is pregnant (if you are male)**  
The baby may absorb this medicine in the womb and there is a possibility of harm to the baby.
- 2. you have had an allergic reaction to COPEGUS or any of the ingredients listed at the end of this leaflet.**  
Some symptoms of an allergic reaction include: hives, skin rash, swelling of the face, lips or tongue, wheezing or troubled breathing, faintness
- 3. you have a red blood cell disorder, such as thalassaemia or sickle-cell anaemia**
- 4. you have very severe liver disease (hepatic decompensation)**
- 5. the package is torn or shows signs of tampering**
- 6. the expiry date printed on the pack has passed**  
If you take this medicine after the expiry date has passed it may not work as well.

**If you are not sure if you should be taking COPEGUS, talk to your doctor.**

### ***Use in children***

**COPEGUS is not recommended for use in children and adolescents under the age of 18.**

The safety and effectiveness of COPEGUS in children and adolescents under 18 years of age have not been established.

### ***Before you start to take COPEGUS***

**Tell your doctor if:**

- 1. you or your female partner are pregnant or plan to fall pregnant**

COPEGUS tablets can cause harm to an unborn baby. You **MUST NOT** take COPEGUS if you are pregnant. You **MUST NOT** take COPEGUS if you are the male partner of a woman who is pregnant.

Extreme care must be taken to avoid pregnancy during treatment and for 6 months after treatment has been completed. Two forms of effective contraception used at the same time are recommended for both males and females while they are taking COPEGUS. Your doctor can discuss the risks of COPEGUS therapy to an unborn baby with you.

Before starting COPEGUS, female patients and female partners of male patients must have a pregnancy test to show that they are not pregnant.

## **2. you are breast-feeding or plan to breast-feed**

Because of the potential for harm to the baby, a decision must be made to discontinue breastfeeding or not to start taking COPEGUS. You should not breast-feed if you are taking COPEGUS.

## **3. you have any other health problems, especially the following:**

- heart problems, especially if they are not well controlled, or any previous serious heart condition
- low levels of red blood cells (anaemia), white blood cells or blood clotting cells (platelets)
- kidney disorders
- poor liver function
- HIV or AIDS

## **4. you are allergic to any other medicines, foods, dyes or preservatives**

**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 if you are taking any other medicines, including any that you have bought without a prescription from a pharmacy, supermarket or health food shop.**

Some medicines may interfere with COPEGUS. These include:

- antacids (Gaviscon<sup>®</sup>, Mylanta<sup>®</sup>, Titalac<sup>®</sup>, Acidex<sup>®</sup>), a group of medicines used to treat heartburn and indigestion
- azathioprine (Azamun<sup>®</sup>, Imuran<sup>®</sup>), a medicine used to suppress the immune system

You must tell your doctor if you are being treated for Human Immunodeficiency Virus (HIV) infection or Acquired Immune Deficiency Syndrome (AIDS) with:

- zidovudine (Retrovir<sup>®</sup>, Combivir<sup>®</sup>)
- didanosine (Videx<sup>®</sup>)
- stavudine (Zerit<sup>®</sup>)

It is not certain whether COPEGUS will change the way these medicines work. Therefore, your doctor may check your blood regularly to be sure that your HIV infection is not getting worse. If it gets worse, your doctor will decide whether or not your COPEGUS treatment needs to be changed.

Your doctor or pharmacist has 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.**

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## **How to take COPEGUS**

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

They may differ from the information contained in this leaflet.

### ***How much to take***

**Take COPEGUS exactly as your doctor has prescribed.**

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

The usual dose is between four and six 200 mg COPEGUS tablets per day. Your dose will depend on your weight, the type of hepatitis C disease you have and whether you are taking COPEGUS in combination with PEGASYS or ROFERON-A. The daily dose is usually divided so that some tablets are taken in the morning and some in the evening.

Your doctor may do regular blood tests to see if COPEGUS is working or if it is causing side effects. Your dose and the length of time you take COPEGUS may be adjusted, or COPEGUS may be stopped altogether, according to your response.

### ***How to take COPEGUS***

**Swallow the tablets whole with a glass of water.**

**Do not chew the tablets.**

### ***When to take COPEGUS***

**Take COPEGUS during or immediately after a meal, at about the same time each day.**

Taking COPEGUS at the same time every day will help its effect and help you to remember to take your tablets.

### ***How long to take COPEGUS***

**Continue taking COPEGUS until your doctor tells you to stop.**

COPEGUS is usually taken for between 24 and 72 weeks. However your doctor may ask you to take COPEGUS for a different period of time.

### ***If you forget to take COPEGUS***

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Do not double the dose.**

**Otherwise, take it as soon as you remember and then go back to taking it as you would normally.**

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

**If you have trouble remembering when to take your dose, ask your pharmacist for some hints.**

### ***If you take too much COPEGUS (overdose)***

**Immediately telephone your doctor or National Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice, or go to your nearest Accident and Emergency Centre, if you think you or anyone else may have taken too much COPEGUS. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.**

**Keep telephone numbers for these places handy.**

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

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## While you are taking COPEGUS

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### ***Things you must do***

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

**Tell your doctor if you become pregnant while taking COPEGUS or within 6 months of stopping treatment.**

Extreme care must be taken to avoid pregnancy during treatment and for 6 months after treatment.

Female patients taking COPEGUS should use two forms of effective contraception at the same time.

Male patients taking COPEGUS should use condoms and their female partners should also use an effective contraceptive.

Females taking COPEGUS, and the female partners of males taking COPEGUS, must have a pregnancy test each month during treatment and for 6 months after treatment with COPEGUS has stopped.

**Tell your doctor that you are taking COPEGUS if you are going to have any laboratory tests.**

**Tell your doctor if, for any reason, you have not taken COPEGUS exactly as prescribed.**

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

**Tell your doctor if you feel that COPEGUS is not helping your condition.**

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

Your doctor may want to do regular tests to monitor your health.

### ***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 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 a prescription or not without first telling your doctor or consulting a pharmacist.**

### ***Things to be careful of***

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

COPEGUS is not expected to affect your ability to drive a car or operate machinery. However, combination therapy with PEGASYS or ROFERON-A may cause dizziness, drowsiness or light-headedness in some people. Be careful driving or operating machinery until you know how the combination therapy affects you. If you drink alcohol dizziness, drowsiness or light-headedness may be worse.

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## Side effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking COPEGUS.**

COPEGUS helps most people with chronic hepatitis C but it may have unwanted side effects.

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.

**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:**

- loss of appetite or weight loss
- nausea, vomiting, diarrhoea or stomach pain
- hair loss
- itching, rash or dry skin
- tingling or numbness of the hands or feet
- increased or decreased feeling or sensitivity, especially in the skin
- reaction at injection site
- flu-like symptoms such as fever, tiredness/fatigue, chills, muscle or joint pain or headache
- cough or sore throat
- flushing
- increased sweating, night sweats
- dry mouth, thirst
- blocked, runny or bleeding nose
- trouble concentrating or sleeping (insomnia)
- sleepiness, drowsiness
- feeling anxious, nervousness
- irritability (getting easily upset)
- depression (feeling low, feeling bad about yourself or feeling hopeless)
- aggressive behaviour
- impotence or decreased sexual drive

These are the more common side effects of COPEGUS in combination with PEGASYS or ROFERON-A.

**Tell your doctor immediately or go to your nearest Accident and Emergency Centre if you notice any of the following:**

- severe chest pain or difficulty breathing
- fast or irregular heartbeats
- severe changes in emotions or moods
- seeing, feeling or hearing things that are not there
- mental illness with strange or disturbing thoughts or moods
- feeling very depressed or having suicidal thoughts or attempts
- thoughts of causing serious harm to others
- signs of anaemia (e.g. tiredness, headaches, being short of breath when exercising, dizziness and looking pale)
- a red or purple skin rash that spreads; blisters on the skin, mouth or nose; red swollen, sore tongue; unexplained skin pain
- difficulty swallowing
- problems with your eyesight such as blurred or loss of vision, eye inflammation, dryness, or pain

- bleeding or bruising more easily than normal
- ringing or other persistent noise in the ears

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

This is not a complete list of all possible side effects. Your doctor or pharmacist has a more complete list. 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.**

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

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

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## **After taking COPEGUS**

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### ***Storage***

**Store your tablets below 30°C.**

**Keep your tablets in the bottle until it is time to take them.**

If you take the tablets out of the bottle they may not keep well.

**Do not store it, or any other medicine, in a bathroom or near a sink.**

**Do not leave it in the car or on window sills.**

Heat and dampness can destroy some medicines.

**Keep COPEGUS where young children cannot reach it.**

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

### ***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.**

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## **Product description**

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### ***Availability***

COPEGUS comes as a 200 mg film coated tablet.

COPEGUS comes in bottle packs of 168 tablets or 112 tablets.

### ***What COPEGUS looks like***

COPEGUS tablets are light pink to pink, flat, oval shaped, film-coated tablets with RIB and 200 engraved on one side and ROCHE in the other side.

### ***Ingredients***

**Active ingredient** – ribavirin 200 mg



### **Inactive ingredients**

- pregelatinised starch, sodium starch glycolate, microcrystalline cellulose, maize starch, magnesium stearate

The film coating contains

- ethyl cellulose, hydroxypropyl methylcellulose, titanium dioxide, talc, iron oxide yellow, iron oxide red, triacetin

### ***Distributor***

COPEGUS tablets are distributed by:

Roche Products (New Zealand) Limited  
P O Box 12492 Penrose  
Auckland 1642  
NEW ZEALAND

Telephone: (09) 635 1500  
Toll Free: 0800 656 464

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