



## Consumer Medicine Information

# ROFERON<sup>®</sup>-A RBV<sup>™</sup>

Interferon alfa-2a 18 MIU in 0.6 mL solution for injection + 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 ROFERON-A RBV combination pack.

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 you using ROFERON-A RBV against the benefits expected for you.

**If you have any concerns about using 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 ROFERON-A RBV is used for

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ROFERON-A RBV is a combination pack product that contains two medicines. One is called ROFERON-A<sup>®</sup> (interferon alfa-2a, solution for injection) and the other is called COPEGUS<sup>®</sup> (ribavirin, film coated tablets).

ROFERON-A RBV is used to treat chronic hepatitis C, which is a viral infection of the liver.

ROFERON-A belongs to a group of medicines called interferons. It is a similar form of interferon to one of the interferons made naturally by your own immune system as a defence against viruses and tumours. ROFERON-A works by slowing the growth of certain viruses, and by boosting the effects of your own immune system to fight them.

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

ROFERON-A RBV is more effective in chronic hepatitis C than treatment with 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 will end up with some liver damage, but not all will feel sick in the earlier stages of the disease. In some people, the liver becomes badly damaged and scarred. This is called cirrhosis. Cirrhosis can cause the liver to stop working properly.

**Ask your doctor if you have any questions why ROFERON-A RBV has been prescribed for you.**

ROFERON-A RBV is not addictive.

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

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## Before you use ROFERON-A RBV

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## **When you must not use ROFERON-A RBV**

**Do not use ROFERON-A RBV if:**

- 1. you have had an allergic reaction to alfa-interferons, ribavirin or to any of the ingredients listed at the end of this leaflet**
- 2. you or your partner is pregnant**  
The baby may absorb this medicine in the womb and there is a possibility of harm to the baby.
- 3. you have a red blood cell disorder, such as thalassaemia or sickle-cell anaemia**
- 4. you have heart disease, or have had it in the past**
- 5. you have severe kidney disease**
- 6. you have a severe bone marrow disorder**
- 7. you might receive a bone marrow transplant in the near future**
- 8. you have severe liver disease (hepatic decompensation)**
- 9. you have recently been treated with medicines that suppress your immune system**
- 10. you suffer from seizures e.g. epilepsy and/or other nervous system disorders**
- 11. you are a child less than 3 years old**  
A rare but serious condition in newborn babies has been linked with benzyl alcohol, an ingredient in ROFERON-A.
- 12. the package is torn or shows signs of tampering**
- 13. the expiry date printed on the pack has passed**  
If you use this medicine after the expiry date has passed it may not work as well.

**If you are not sure if you should be using ROFERON-A RBV, talk to your doctor.**

## **Use in children**

**ROFERON-A RBV is not recommended for use in children or adolescents under the age of 18.** The safety and effectiveness of ROFERON-A RBV have not been established in children or adolescents under 18 years of age.

## **Before you start to use ROFERON-A RBV**

**Tell your doctor if:**

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

The COPEGUS component of ROFERON-A RBV 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.

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

Extreme care must be taken to avoid pregnancy during treatment and for 6 months after treatment has been completed. Your doctor can discuss the risks of COPEGUS therapy to an unborn baby with you.

- 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 ROFERON-A RBV. You should not breast-feed if you are taking ROFERON-A RBV.

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

- heart problems, especially if they are unstable (not well controlled), or any previous serious heart condition
- low levels of red blood cells, white blood cells or platelets (blood clotting cells)
- poor kidney or liver function
- HIV or AIDS
- bone marrow disease or bone marrow suppression
- you have had an organ transplant (eg kidney or bone marrow) or an organ transplant is planned for you in the immediate future
- autoimmune disease (a disease where your immune system attacks your own cells and tissues), or hepatitis with a history of autoimmune disease
- depression or any other mental illness, or a history of depression or other mental illnesses
- psoriasis (a skin disease)
- raised blood sugar levels or diabetes
- high blood pressure (hypertension)
- recent infection with persistent fever

**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 using ROFERON-A RBV.**

***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 interfere with ROFERON-A RBV.

You must tell your doctor if you are taking theophylline (a medicine used in the treatment of asthma, bronchitis, emphysema and related conditions) as you may need to take a different dose of ROFERON-A. Your doctor will advise you.

If you are also being treated for Human Immunodeficiency Virus (HIV) infection (AIDS) with zidovudine (Retrovir<sup>®</sup>, Combivir<sup>®</sup>), didanosine (Videx<sup>®</sup>) or stavudine (Zerit<sup>®</sup>), it is not certain if the COPEGUS component of ROFERON-A RBV will change the way these medicines work. Therefore, your blood may be checked regularly to be sure that the HIV infection is not getting worse. If it gets worse, your doctor will decide whether or not your ROFERON-A RBV treatment needs to be changed.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using ROFERON-A RBV.

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

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**How to use ROFERON-A RBV**

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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 to use ROFERON-A***



The ROFERON-A component of ROFERON-RBV can be given by your doctor, nurse or pharmacist, or your doctor, nurse or pharmacist may teach you how to inject yourself with ROFERON-A. Do not try to inject yourself with ROFERON-A unless you have received training.

ROFERON-A comes in a cartridge (18MIU) which can be used more than once (multi-dose).

The ROFERON-A cartridge is designed to be used with the Roferon-Pen device. **Information on how to use the Roferon-Pen/cartridge combination is provided in the user manual supplied with the device.** Read this manual carefully before use. You should write the date of first use on the label provided with the cartridge and use within 28 days of this date. A new sterile needle must be used each time you administer a dose from the Roferon-Pen.

Your doctor or nurse will show you a "sterile technique" that will allow you to administer the required amount of ROFERON-A safely.

### ***How much ROFERON-A to inject***

**Inject ROFERON-A exactly as your doctor or nurse has prescribed.**

The dosage of ROFERON-A is expressed in Millions of International Units (MIU).

The dose of ROFERON-A will be determined by your doctor. The usual dose ranges from 3 MIU to 4.5 MIU three times a week.

The dosage may be adjusted by your doctor depending on your response to treatment.

Your doctor will keep track of your response to ROFERON-A by asking questions and performing laboratory tests as needed.

**Do not exceed or change the dose recommended by your doctor.**

### ***How to inject ROFERON-A***

ROFERON-A is normally administered by subcutaneous injection i.e. it is injected into the tissue just under the skin. You may be able to give yourself the injections at home.

#### **Directions for self-administration**

Your doctor, nurse or pharmacist may discuss whether it would be more convenient for you to receive your injections at home, in which case you or a family member will be instructed on how to give the injection properly. This is a simple procedure and many people prefer it.

If you have decided to inject ROFERON-A at home, please follow the instructions your doctor, nurse or pharmacist has given you carefully.

**Refer to the instruction manual that is provided with the ROFERON-Pen.**

You should read the instructions enclosed within the ROFERON-Pen pack from beginning to end before starting so that each step of the procedure becomes familiar. These instructions must be carefully followed. Consult your doctor if you require further instructions.

Remember that cleanliness is vital when preparing and injecting ROFERON-A.

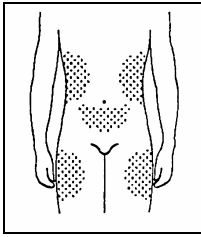
#### ***I. Before a subcutaneous injection***

- Check the expiry date. Do not use ROFERON-A after the expiry date shown on the cartridge label.
- Check the dose you have been prescribed.
- Check the liquid has no discolouration, cloudiness or particles. The liquid should look clear and colourless to slightly yellow.

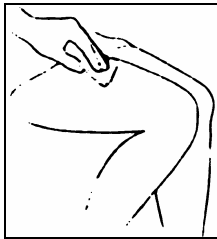
- Remove the ROFERON-A cartridge from the fridge and let stand for 30 minutes at room temperature. You can gently warm the cartridge in the palms of your hands for about 1 minute however be careful not to shake the medication.
- Place everything you need on a clean surface within easy reach: the cartridge, the needle for injection, two alcohol swab packets and a container for disposal of the needle.

## **II. Performing subcutaneous injection**

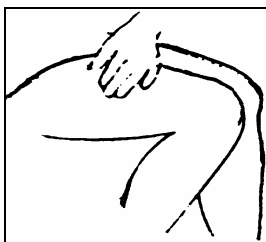
1. Wash your hands thoroughly.
2. Choose an injection site. The sides of the thigh and stomach, except for the belly button (see diagram below) are suitable areas. Change your injection site each time you use the pen to avoid the risk of soreness at any one site.



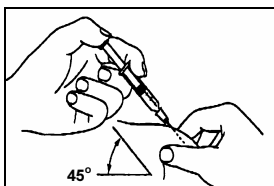
3. Remove an alcohol swab from one packet and clean and disinfect the site by wiping with the swab.



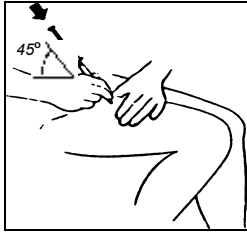
4. Remove the alcohol swab from the site. Allow the injection site to dry for 10 seconds.
5. Grasp the skin firmly between your thumb and forefinger (without squeezing) to elevate the subcutaneous tissue.



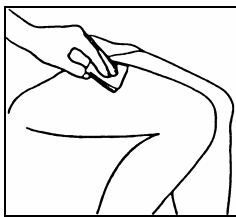
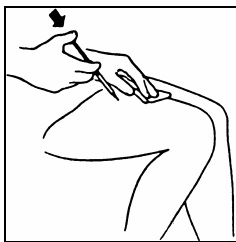
6. Insert the needle fully into the skin at an angle of approximately 45°.



7. Inject by pressing the dosage knob until it stops and locks. Keep fully pressed for five seconds



8. After injecting, withdraw the needle from the skin at the same angle so it does not hurt you, and release the skin. Immediately disinfect the site with a new alcohol swab and apply finger pressure over the swab for a minute or so.



Do not be concerned if you see slight bleeding. If it does bleed, keep pressing on the area. Check the site later for any signs of soreness, and if this occurs tell your doctor or nurse at the next opportunity.

*Remember:* Most people can learn to give themselves a subcutaneous injection, but if you experience difficulty, please do not be afraid to ask for help and advice from your doctor, nurse or pharmacist.

### **III. How to dispose of used needles**

The needle of the Roferon-Pen is to be used **once only**. Dispose of the needle immediately after injection into a sturdy glass or hard plastic container or specified “sharps” container. Do not replace the needle cover.

**Never** put used needles into your normal household waste bin.

If you are not sure how to dispose of the needles, consult your doctor, nurse or pharmacist.

### **When to inject ROFERON-A**

Your doctor will tell you how often to use this medicine. ROFERON-A is usually injected three times a week.

If you are injecting this medicine yourself, use it at bedtime as ROFERON-A may make you very tired or cause flu-like symptoms.

### **How much COPEGUS 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. The dose depends on your weight and the type of hepatitis C disease you have. 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 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 use ROFERON-A RBV***

**Continue using ROFERON-A RBV until your doctor tells you to stop.**

Your ROFERON-A RBV treatment period is usually between 24 and 48 weeks. However your doctor may instruct you to take ROFERON-A RBV for a different period of time. Your doctor will determine when your treatment should be stopped.

### ***If you forget to use your ROFERON-A RBV***

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

**Otherwise, use your medicine as soon as you remember, and then go back to using 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 use your medicine, ask your pharmacist for some hints.**

### ***If you use too much ROFERON-A RBV (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 that you or anyone else may have used too much ROFERON-A or COPEGUS, 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 using ROFERON-A RBV**

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

**Tell all doctors, dentists and pharmacists who are treating you that you are using ROFERON-A RBV.**

**Tell your doctor if you become pregnant while using ROFERON-A RBV.**



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

Females taking ROFERON-A RBV, and the female partners of males taking ROFERON-A RBV, must have a pregnancy test each month during treatment and for 6 months after treatment with ROFERON-A RBV has stopped to show that they are not pregnant.

Female patients taking ROFERON-A RBV should use two forms of effective contraception at the same time.

Male patients taking ROFERON-A RBV should use condoms and their female partners should also use an effective contraceptive.

**Tell your doctor that you are taking ROFERON-A RBV if you are going to have any laboratory tests.**

**Tell your doctor if, for any reason, you have not used ROFERON-A RBV 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 ROFERON-A RBV is not working for you.**

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

Your doctor will keep track of your response to ROFERON-A RBV by asking questions and performing occasional laboratory tests.

### ***Things you must not do***

**Do not stop using ROFERON-A RBV 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 ROFERON-A RBV to anyone else even if they have the same condition as you.**

**Do not use ROFERON-A RBV to treat other complaints unless your doctor says to.**

**Do not switch to any other brand of interferon without consulting your doctor first.**

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

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

ROFERON-A RBV may cause dizziness, drowsiness or light-headedness in some people, or cause them to become confused. Be careful driving or operating machinery until you know how ROFERON-A RBV 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 using ROFERON-A RBV.**

ROFERON-A RBV helps most people with chronic hepatitis C but it may have unwanted side effects in some 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.



**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:**

- weight loss, taste changes, indigestion
- mild to moderate hair loss (usually reversible after finishing treatment)
- itching, rash or dry skin
- headache or dizziness
- muscle or joint pain
- cough or sore throat
- tiredness, weakness
- fever, chills or shaking
- trouble concentrating, remembering things or sleeping (insomnia)
- irritability or anxiety
- nervousness
- blurred vision, eye pain or dryness
- blocked, runny or bleeding nose
- bleeding or bruising more easily than normal
- tender or bleeding gums
- decrease in sex drive/desire, impotence
- flu-like symptoms such as fatigue, fever, chills, appetite loss, muscle or joint pain, headache and sweating (these symptoms occur frequently and can usually be relieved by paracetamol)

These are the more common side effects of ROFERON-A RBV .

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

- chest pain, fast or irregular heart beats
- breathlessness which may be severe and usually worsens on lying down
- depression (feelings of deep sadness and unworthiness, or feeling “down”)
- strange or disturbing thoughts or moods
- suicidal thoughts or attempt
- signs of anaemia (e.g. tiredness, headaches, being short of breath when exercising, dizziness and looking pale)
- nausea, vomiting, diarrhoea or stomach pain
- constipation, blood in the stools
- loss of consciousness
- visual disturbances or loss of vision
- seeing, feeling or hearing things that are not there
- excessive thirst, the passing of a greatly increased amount of urine, increase in appetite with a loss of weight, feeling tired, drowsy, weak, depressed, irritable and generally unwell.
- sudden signs of allergy such as a red, itchy, blistering rash similar to measles, which may occur in the mouth or on hands and forearms; itching or hives on the skin; swelling of the face; lips, tongue or other parts of the body; shortness of breath; wheezing or trouble breathing

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

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 using ROFERON-A RBV

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### **Storage of ROFERON-A RBV**

**The ROFERON-A RBV pack should be stored in the refrigerator prior to use.**

Once the ROFERON-A RBV pack has been opened, the COPEGUS film coated tablet pack may be removed and stored separately below 30°C. COPEGUS film coated tablets do not need to be kept in the refrigerator.

Prior to use, ROFERON-A cartridges should be kept in the closed original pack stored in the fridge at 2 - 8°C. Do not freeze. The top shelf of the refrigerator is a good place to store the injection.

When the cartridge is installed in the Roferon-Pen, or placed in the specially designed carrying case provided with the Pen, the multi-use cartridge can be stored at room temperature (below 25°C) for up to 28 days. However, where possible, cartridges should be stored in the fridge (2 - 8°C) and returned to the fridge after each injection. Never freeze the Roferon-Pen or its case when containing a cartridge.

Cartridges should be used within 28 days of the first withdrawal.

**Do not shake ROFERON-A cartridges.**

**Protect ROFERON-A cartridges from light.**

**Always keep ROFERON-A in its carton and COPEGUS tablets in their bottle until it is time to take your medicine.** If you take the tablets out of the bottle they may not keep well.

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

**Do not leave ROFERON-A RBV in the car or on window sills.** Heat and dampness can destroy some medicines.

**Keep ROFERON-A RBV 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 COPEGUS tablets.

### ***Disposal***

**If your doctor tells you to stop using ROFERON-A RBV, or the injection or tablets have passed their expiry date, ask your pharmacist what to do with any cartridges or tablets that are left over.**

**If you are injecting ROFERON-A at home, you must throw away the needles or cartridges into a sturdy glass or hard plastic container that will not let the needles stick through it or a specified "sharps" container. This will help protect you and other people from accidental needle stick injuries. Being pricked by a needle can pass disease onto other people.**

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## Product description

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### ***Availability***

The ROFERON-A RBV combination pack is available in two sizes and each pack contains a sticker for recording the date of first withdrawal from the cartridge.

### ***ROFERON-A RBV Combination Therapy Starter Pack***

Each pack contains:  
2 boxes of ROFERON-A multidose cartridges  
1 Roferon-Pen injector



1 pack of 100 needles  
1 bottle of 168 COPEGUS 200 mg film coated tablets

***Roferon-A RBV Combination Therapy Packs***

Each pack contains:  
2 boxes of ROFERON-A multidose cartridges  
1 bottle of 168 COPEGUS 200 mg film coated tablets

***What ROFERON-A looks like***

ROFERON-A solution for injection is contained in a glass cartridge. The solution is clear and colourless to slightly yellowish.

**Ingredients**

**Active ingredient** - interferon alfa-2a

**Inactive ingredients** - ROFERON-A solution for injection also contains ammonium acetate, sodium chloride, benzyl alcohol (1% w/v), polysorbate 80, glacial acetic acid, sodium hydroxide, water for injection.

***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

**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***

ROFERON-A RBV combination packs are distributed by:

Roche Products (New Zealand) Ltd  
P O Box 12-492  
Penrose  
AUCKLAND 1642

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

This leaflet was prepared on 6 August 2008.

**Reference: ROFERON-A RBV New Zealand Data Sheet dated 6 August 2008.**