New Zealand Consumer Medicine Information

ROFERON®-A

Interferon alfa-2a

3 million IU (MIU) in 0.5 mL prefilled syringes for injection

What is in this leaflet

This leaflet answers some common questions about ROFERON-A.

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 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.

What ROFERON-A is used for

ROFERON-A contains an active ingredient called interferon alfa-2a.

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 tumour cells and viruses, and by boosting the effects of your own immune system to fight them.

ROFERON-A is used in the treatment of viral infections of the liver (chronic active hepatitis B and chronic hepatitis C).

ROFERON-A treatment will not prevent a hepatitis B or C infected person from giving another person hepatitis B or C.

When used for treating hepatitis C, ROFERON-A is sometimes used in combination with a medicine called COPEGUS® (ribavirin). If you are also taking COPEGUS, please read the Consumer Medicine Information for COPEGUS – it contains important information on how to use COPEGUS safely.

ROFERON-A is also used in the treatment of various types of cancer such as kidney cancer (renal cell carcinoma), cancer of the lymph glands (cutaneous T-cell lymphoma), blood cancer (hairy cell leukaemia, chronic lymphocytic leukaemia (CLL), chronic myelogenous leukaemia (CML), multiple myeloma and other bone marrow conditions causing platelet disorders), skin cancer (malignant melanoma, basal cell carcinoma), non-Hodgkin's lymphoma and AIDS-related cancer (Kaposi's sarcoma).

ROFERON-A may be used in combination with AVASTIN® (bevacizumab) for the treatment of kidney cancer.

Your doctor, however, may have prescribed ROFERON-A for another reason.

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

ROFERON-A is not addictive.

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

Before you use ROFERON-A

When you must not use ROFERON-A

Do not use ROFERON-A if:

1. **you have had an allergic reaction to alfa-interferons or to any of the ingredients listed at the end of this leaflet**

   Some symptoms of an allergic reaction include:
   - shortness of breath
   - wheezing or breathing difficulties
   - swelling of the face, lips, tongue or other parts of the body
   - rash, itching or hives on the skin

2. **you have heart disease, or have had it in the past**
3. **you have severe kidney disease or liver disease**
4. **you have a severe bone marrow disorder**
5. **you might receive a bone marrow transplant in the near future**
6. **you have hepatitis and advanced liver disease**
7. **you have hepatitis and have recently been treated with medicines that suppress your immune system**
8. **you suffer from seizures e.g. epilepsy and/or other nervous system disorders**
9. **the package is torn or shows signs of tampering**
10. **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 talk to your doctor.

Use in children

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

A rare but serious condition in newborn babies has been linked with benzyl alcohol, an ingredient in ROFERON-A. Therefore, this product should not be given to babies from birth up to the age of 3 years.

Before you start to use ROFERON-A

Tell your doctor if:

1. **you are pregnant or plan to become pregnant**

It is not known whether ROFERON-A is harmful to an unborn baby when used by a pregnant woman. If there is a need to use ROFERON-A when you are pregnant your doctor will discuss the risk and benefits to you and the unborn baby.

Both males and females are recommended to use effective contraception while taking ROFERON-A.

ROFERON-A used in combination with ribavirin (COPEGUS) must not be used in pregnant women. Please refer to the Consumer Medicine Information for COPEGUS for further information.

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

Because interferon alfa-2a occurs naturally in the body, it has not been possible to determine whether ROFERON-A passes into the breast milk following injection. Breast-feeding is not recommended while taking ROFERON-A. Your doctor will discuss with you whether to stop breast-feeding or stop taking ROFERON-A.

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

- poor kidney or liver function
- bone marrow disease or bone marrow suppression
- you have had an organ transplant (e.g. 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
- eye problems, including trouble with your vision

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.

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.

Some medicines interfere with ROFERON-A.

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.

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

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

How to use ROFERON-A

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

ROFERON-A 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 single-use prefilled syringes.

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

Use 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 based on your condition. The usual dose ranges from 1.5 MIU to 18 MIU. The dosage is unlikely to exceed 36 MIU on any one day. Your doctor will tell you how many times a week to take ROFERON-A.

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.

If you are receiving other treatments for your disease (e.g. chemotherapy, AVASTIN), your ROFERON-A injection may be given by a doctor or nurse whilst you are in hospital receiving your other treatment.

Directions for subcutaneous self-administration

It may be appropriate and more convenient for you to receive your injections at home. Your doctor, nurse or pharmacist will discuss this with you. If this is the case, you or a family member will be instructed on how to give the injection properly. This is a simple procedure and many patients prefer to administer their treatment at home. Administration of the subcutaneous injection is described further on in this leaflet.

You should read these directions from beginning to end before starting so that each step of the procedure becomes familiar. These instructions must be carefully followed. Consult your doctor, nurse of pharmacist if you require further instructions.

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

How to inject with the prefilled syringe

I. Before a subcutaneous injection

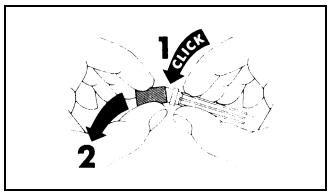
- Check the expiry date. Do not use ROFERON-A after the expiry date shown on the prefilled syringe label.
- Check the dose you have been prescribed.
- Check the liquid has no discolouration, cloudiness or particles. The liquid should look clear and colourless to slightly yellow.
- Remove the ROFERON-A syringe from the fridge and let it stand for 30 minutes at room temperature. You can gently warm the syringe 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 prefilled syringe, the needle for subcutaneous injection, two alcohol swab packets and a container for disposal of the needle and syringe.

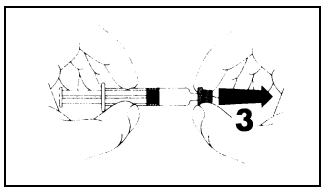
II. How to prepare the syringe

1. Wash your hands thoroughly.

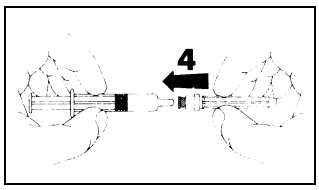
2. Take the sealed needle in both hands and snap the grey cap backwards. Remove the grey cap. *Do not* remove the plastic needle shield.



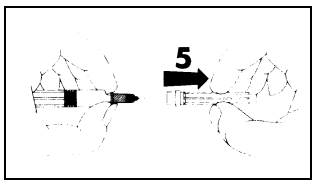
3. Remove the rubber cap from the syringe. *Do not* touch the tip of the syringe.



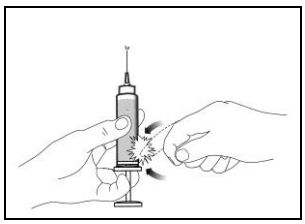
4. Attach the needle with the plastic shield firmly to the syringe.



5. Remove the plastic cover from the needle while holding the syringe. Avoid pushing the plunger.



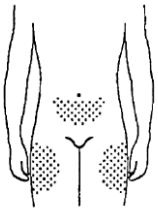
6. To remove air bubbles from the syringe, hold the syringe with the needle pointing up. Tap the syringe gently to bring the bubbles to the top. If your dose is less than that contained in the syringe push the plunger up slowly to the correct dose. Carefully replace the needle guard and place the syringe in a horizontal position on a clean flat surface.



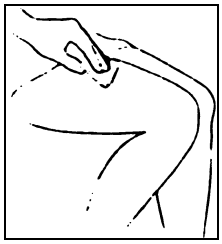
The syringe is now ready for use.

III. Performing a subcutaneous injection

7. Choose an injection site. The most suitable places for injection are the top of the thighs and the abdomen, except for the belly button area (see diagram below). Change your injection site each time to avoid the risk of soreness at any one site.

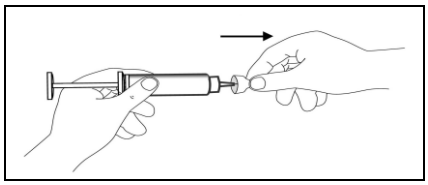


8. Remove an alcohol swab from one packet and clean and disinfect the site by wiping with the swab.

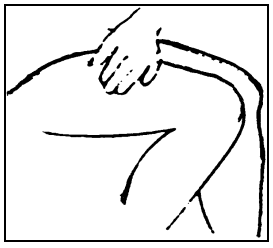


9. Remove the alcohol swab from the site. Allow the injection site to dry for 10 seconds.

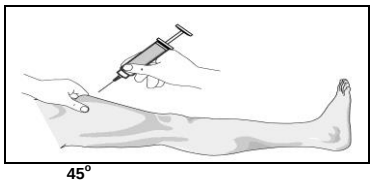
10. Remove the needle guard.



11. Grasp the skin firmly between the thumb and forefingers (without squeezing) to elevate the subcutaneous tissue. With your other hand, hold the syringe as you would a pencil.



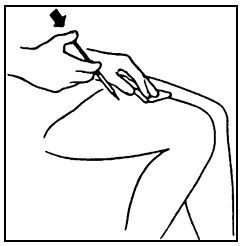
12. Gently insert the needle into the grasped skin at an angle of approximately 45º (bevelled edge facing upwards). Half of the needle should still be visible.

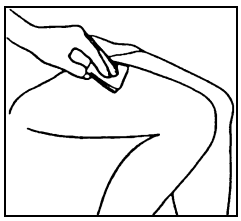


Pull back slightly on the plunger to check that a blood vessel has not been punctured. If you see blood in the syringe, remove the needle and insert it in another place.

13. Inject the liquid slowly and continuously by gently pushing the plunger down while keeping the skin grasped.

14. After injecting, remove the needle 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.

IV. How to dispose of used needles and syringes

The needle and prefilled syringe are to be used **once** only. Dispose of the needle and syringe 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 and syringes into your normal household waste bin.

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

When to inject ROFERON-A

Your doctor will tell you how often to use this medicine. ROFERON-A is usually injected a maximum of one injection per day.

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 long to use ROFERON-A

Your ROFERON-A treatment period could range from a few weeks up to 12 months or more depending on your illness.

If your injections are administered at a hospital with another treatment (e.g. chemotherapy, AVASTIN), your ROFERON-A treatment might continue for several months after your other treatment has stopped. At this time, you may start to self-administer ROFERON-A as described above. Your doctor will advise you.

Continue using ROFERON-A until your doctor tells you to stop.
Your doctor will determine when your treatment should be stopped.

If you forget to use ROFERON-A

If it is almost time for your injection, skip the injection you missed and use your next injection 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.

In case of 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, 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.

While you are using ROFERON-A

Things you must do

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

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

Both males and females are recommended to use effective contraception while taking ROFERON-A.

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

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

Things you must not do

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

Do not use ROFERON-A 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 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 affects you. If you drink alcohol, dizziness, drowsiness or light-headedness may be worse.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using ROFERON-A.

ROFERON-A helps most people but it may have unwanted side effects.

All medicines can have side effects. Sometimes they are serious. 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:

- 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)
- anxiety (feeling nervous or anxious)
- abnormal thoughts or behaviour
- loss of appetite, taste change, dry mouth, weight loss
- tiredness, weakness, lack of energy, drowsiness
- mild to moderate hair loss (usually reversible after finishing treatment)
- dizziness or vertigo (a spinning sensation)
- temporary impotence
- reappearance of cold sores if you have previously been infected with herpes virus

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

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

- depression (feelings of deep sadness and unworthiness, or feeling “down”)
- thoughts about harming yourself, suicidal thoughts or attempts
- confusion, trouble sleeping, thinking or concentrating
- mania (episodes of overactivity, elation or irritability, excitement, over-activity and uninhibited behaviour)
- chest pain, fast or irregular heartbeat
- weakness, numbness or tingling sensation
- breathlessness which may be severe and usually worsens on lying down
- swelling of the hands, feet or ankles
- visual disturbances or loss of vision
- convulsions (epileptic fits)
- tremor (shaking)
- anaemia – signs include tiredness, headaches, being short of breath when exercising, dizziness and looking pale
- bleeding or bruising more easily than normal
- frequent infections (symptoms include fever, severe chills, sore mouth or mouth ulcers)
- dizziness or light-headedness (a sign of low blood pressure or hypotension)
- hypertension (high blood pressure) signs include headache, blurred vision or facial flushing)
- passing little or no urine
- serious lung infection with fever, chills, shortness of breath and cough with phlegm and/or occasionally blood
- a blue, grey, or dark purple discoloration of the lips, fingers or toes
- loss of consciousness
- nausea, vomiting, diarrhoea, mild to moderate abdominal (gut) pain, severe upper stomach pain
- 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
- symptoms of bowel inflammation including diarrhoea (usually with blood or mucus), stomach pain, fever

- sudden signs of allergy such as rash, 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. 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.

After using ROFERON-A

Storage of ROFERON-A

Prior to use, ROFERON-A prefilled syringes should be kept in the closed original pack stored in the fridge at 2 – 8 ^{o}C. Do not let ROFERON-A freeze. Protect from light.

Do not shake ROFERON-A prefilled syringes.

Protect ROFERON-A from light.

Do not leave ROFERON-A in the car or on windowsills. Heat and dampness can destroy some medicines.

Keep ROFERON-A where young children cannot reach it. The top shelf of the refrigerator is a good place to store this medicine.

ROFERON-A prefilled syringes are for single use only. Each prefilled syringe should be used only once and any remaining contents should be discarded along with the syringe and the needle.

Disposal

If your doctor tells you to stop using ROFERON-A, or the product has passed its expiry date, ask your pharmacist what to do with any prefilled syringes that are left over.

If you are injecting ROFERON-A at home, you must throw away the needles and syringes 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.

Product description

Availability

ROFERON-A prefilled syringes are available in packs of one. Each pack contains the prefilled syringe and one needle for subcutaneous injection.

What ROFERON-A looks like

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

A stainless steel needle is supplied with the syringes for subcutaneous injection.

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.

ROFERON-A prefilled syringes are presented in the following strengths:

- 3.0 MIU in 0.5 mL of solution

Distributor

ROFERON-A prefilled syringes are distributed by:

Roche Products (New Zealand) Limited
PO Box 109113
Newmarket, Auckland 1149
NEW ZEALAND

Medical Enquiries: 0800 656 464

This leaflet was prepared on 30 October 2015