

**Roferon-A
Pre-filled Syringe****Roche**

Interferon alfa-2a

Roferon-A 3MIU/0.5ml Pre-filled Syringes containing solution for injection.
Roferon-A 4.5MIU/0.5ml Pre-filled Syringes containing solution for injection.
Roferon-A 6MIU/0.5ml Pre-filled Syringes containing solution for injection.
Roferon-A 9MIU/0.5ml Pre-filled Syringes containing solution for injection.
Roferon-A 18MIU/0.5ml Pre-filled Syringes containing solution for injection.

This leaflet contains information for patients being treated with Roferon-A. Please read this leaflet carefully before you start to take your medicine. If you have any questions or are not sure about anything, ask your doctor, nurse or pharmacist.

What is Roferon-A?

Roferon-A contains an antiviral agent called interferon alfa-2a which is similar to a natural substance produced by the body to protect against viral infections. Roferon-A solution for injection contains the additional ingredients of ammonium acetate, sodium chloride, 1% benzyl alcohol (as preservative), polysorbate 80, glacial acetic acid, sodium hydroxide solution and water for injections. (Sodium content 0.123mmoles/ml).

Roferon-A is available as pre-filled syringes for subcutaneous injection in packs of 1. One pre-filled syringe contains 3, 4.5, 6, 9 or 18 million international units (MIU) interferon alfa-2a in 0.5ml ready-to-use solution for injection. The pre-filled syringes are for single-dose self administration. Injection swabs (alcohol wipes) may be supplied with the product.

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What is Roferon-A used for?

Roferon-A is used for the treatment of some viral infections such as chronic hepatitis B and C. Roferon-A has also been shown to stop the growth of certain types of cells and may be used to treat certain cancers of the blood (cutaneous T-cell lymphoma, hairy cell leukaemia, chronic myelogenous leukaemia) or other forms of cancer (renal cell carcinoma, AIDS-related Kaposi's sarcoma, follicular non-Hodgkin's lymphoma, malignant melanoma). If you are not sure why you have been prescribed Roferon-A, you should discuss your illness and its treatment with your doctor.

When must Roferon-A not be used?

- if you are allergic to Roferon-A or any of the ingredients it contains.
- if you suffer or have suffered from heart disease.
- if you have a severe kidney or liver condition.
- if you have a bone marrow disorder.
- if you suffer from seizures e.g. epilepsy and/or other nervous disorders.

Roferon-A is not recommended for use by children except on the advice of your doctor. A serious condition in children up to 3 years old, "gasping syndrome" has been linked with benzyl alcohol (an inactive ingredient in Roferon-A solution for injection) and, therefore, Roferon-A solution for injection is not a suitable medicine for young children.

For some diseases Roferon-A may be used in combination with other drugs. In such cases any additional restrictions on the use of Roferon-A will be explained to you by your doctor.

When should you be extra careful when using Roferon-A?

Make sure your doctor knows if you:

- have psychiatric difficulties or have ever had a psychiatric illness.
- have psoriasis.
- have kidney, heart or liver problems.
- have an autoimmune disease e.g. thyroid dysfunction, vasculitis.
- have had an organ transplant (e.g. kidney) or bone marrow transplant or have one planned in the near future.
- are or may be pregnant.
- have severe low blood count.
- are taking other medicines (including those not prescribed by your doctor).
- suffer from diabetes (high sugar level in your blood).
- have any other blood disorders.

If you have a blood disorder or suffer from diabetes, your doctor may take samples of your blood at intervals to check its composition which may change during treatment. If so, your doctor may adapt the dose of your treatment with Roferon-A and any other treatments you are receiving at the same time.

If you develop signs of a severe allergic reaction (such as difficulty in breathing, wheezing or hives) while on this medication, seek medical help immediately.

If you notice a decrease in your sight after or during treatment with Roferon-A, contact your doctor immediately.

If you develop any signs of depression such as sadness, feeling worthless, or thoughts of suicide during your Roferon-A treatment, contact your doctor immediately.

You may find that your ability to drive a car or operate machinery is affected. Therefore make sure that you know how you have reacted to Roferon-A before you drive a car or operate machinery.

May Roferon-A be used during pregnancy or while breast feeding?

The use of Roferon-A during pregnancy should be avoided. You and your partner should therefore practise effective contraception for the duration of your treatment with Roferon-A alone. Before starting treatment, you must tell your doctor if you are pregnant, if you think you are pregnant or if you intend to become pregnant, as it is possible that taking Roferon-A when you are pregnant may harm your unborn baby.

When it has been decided to combine Roferon-A with ribavirin you must read the instructions given with ribavirin for further information on contraception during and after treatment. Ribavirin has the potential to cause damage to your unborn child. Therefore, you must not be and must not become pregnant during ribavirin therapy and for an appropriate period thereafter (see ribavirin patient information leaflet for further details). You should record a negative pregnancy test immediately before starting treatment.

Because alfa-interferon occurs naturally throughout the body, it has not been possible to determine whether Roferon-A passes into the breast milk following injection. Therefore, your doctor may decide that you should not use Roferon-A if you are breast-feeding.

How should Roferon-A be used?

Roferon-A can be given by your doctor or nurse, or your doctor or nurse may teach you how to inject yourself with Roferon-A. Do not try to inject yourself with Roferon-A unless you have received training. It is important to always take this medicine exactly as your doctor tells you to.

Roferon-A pre-filled syringes are used to give an injection, beneath your skin (subcutaneous).

The amount of Roferon-A you need will depend on the illness for which you are being treated and any side-effects you are experiencing. Your doctor will decide which dose is best for you. Your dosage should not normally exceed 36 Million International Units (MIU) per day.

Do not change the prescribed dose yourself. If you think the effect of your medicine is too weak or too strong, talk to your doctor.

Disease	Usual Initial Dosage Regime
Hairy Cell Leukaemia	3MIU daily for 16 - 24 weeks.
Chronic Myelogenous Leukaemia	The dose will normally be increased from 3MIU to 9MIU taken once a day over an initial treatment period of 12 weeks.
Cutaneous T-Cell Lymphoma	The dose will normally be increased from 3MIU to 18MIU taken once a day over an initial treatment period of 12 weeks.
AIDS-Related Kaposi's Sarcoma	The dose will normally be increased from 3MIU to 18MIU taken once a day to a maximum of 36MIU over an initial treatment period of 10 - 12 weeks.
Renal Cell Carcinoma	The dose will normally be increased from 3MIU to 18MIU taken three times a week over an initial treatment period of 12 weeks.
Chronic Hepatitis B	2.5 - 5MIU/square metre body surface area three times a week for 4 - 6 months.
Chronic Hepatitis C	3 - 6MIU three times a week for 6 months.
Follicular Non-Hodgkin's Lymphoma	With chemotherapy: 6MIU/square metre body surface area from day 22 to day 26 of each 28-day cycle.
Malignant Melanoma	3MIU three times a week for 18 months.

If you respond well to initial treatment with Roferon-A (guidance on usual doses given above) your doctor may decide that you should continue to receive treatment for a longer period of time (maintenance therapy) and will adjust your dosage accordingly.

The pre-filled syringes are intended for single use. You should discard any unused product or waste material. Ask your doctor or pharmacist for further advice.

If you take too much medicine or someone else accidentally takes your medicine, contact your doctor, pharmacist or nearest hospital straight away.

When and how does treatment with Roferon-A end?

Your doctor will tell you when to stop using Roferon-A. Some illnesses may require treatment over a period of several years.

It is quite permissible to start taking Roferon-A again if your doctor prescribes it.

What are the possible undesirable effects of Roferon-A?

In addition to the beneficial effects of Roferon-A, it is likely that undesirable effects will occur during treatment, even when it is used as directed.

General symptoms:

It is common to experience flu-like symptoms such as tiredness, chills, appetite loss, muscle or joint pain, headache, sweating and fever. These effects can usually be reduced by taking paracetamol and your doctor will advise you on the dose you should take. These kind of symptoms usually lessen with continued therapy. Pneumonia or increased blood sugar levels may occur in very rare cases.

Gastro-intestinal tract:

Loss of appetite and nausea are side-effects which occur frequently. Other side-effects which may affect the stomach and bowel such as abdominal pains, diarrhoea, vomiting, heartburn, constipation, weight loss, flatulence, reactivation of a peptic ulcer, taste alteration and dry mouth have been observed less frequently. Rarely intestinal bleeding has occurred..

Nervous system:

Uncommon dizziness, pins and needles, trembling, numbness, sleep disturbances, anxiety states, forgetfulness, drowsiness, confusion, depression, and suicidal behaviour have occurred. You should inform your doctor if you experience any symptoms of depression.

Rarely vertigo, transient or temporary impotence, convulsions and coma have been reported.

Skin and mucous membranes:

Rash, dryness or itching of your skin, cold sores, genital herpes, runny nose and nose bleeds may occur. Hair thinning or hair loss sometimes occurs but this is usually reversible on completion of treatment.

Other side-effects:

Sometimes mild effects on your liver may be observed and these will not normally require a change in dosage. In rare cases, severe liver abnormalities have occurred after treatment with Roferon-A. In rare cases Roferon-A may cause the kidneys to work less well than usual.

Increases in enzyme levels from the pancreas have occurred in rare cases.

Visual disturbances have been reported and very rarely, loss of eyesight.

A reduction in the amount of platelets (required for clotting) in the blood leading to small bruises on the body or bleeding have been rarely reported.

Autoimmune phenomena (where the body attacks its own cells) such as vasculitis (inflammation of the blood vessels), arthritis, haemolytic anaemia (a decrease in the number of red blood cells) and abnormal function of the thyroid gland have been rarely reported.

Sarcoidosis (a disease that results from inflammation of tissues of the body) has been very rarely reported. Sarcoidosis can affect almost any body organ, but most often starts in the lungs or lymph nodes.

Temporary low or high blood pressure, chest pain and palpitations have been observed by patients taking Roferon-A. Serious heart and lung problems occur very rarely.

Some changes may occur in your blood which your doctor will check for.

You may get a slight reaction around the area of skin where you are injected with Roferon-A. This may cause dead tissue to occur in rare cases.

Your doctor may decide to combine your Roferon-A treatment with other medicines. In such cases you may experience additional undesirable effects. Where these may occur they will be explained to you by your doctor.

If you are concerned about these or any other unwanted effects talk to your doctor or pharmacist.

How should Roferon-A be stored?

- Roferon-A should be stored in the fridge at 2 - 8°C. Do not let it freeze.
- Always keep this medicine in the closed original pack.
- Keep this medicine out of the reach and sight of children.
- This medicine must not be used after the date (EXP) printed on the pack. Return any left-over medicine to your pharmacist. Only keep it if your doctor tells you to.
- **REMEMBER** this medicine is for you. Only a doctor can prescribe it for you. Never give it to others. It may harm them even if their symptoms are the same as yours.

Further information:

You can get more information on Roferon-A Pre-filled Syringes from your doctor, nurse or pharmacist.

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