European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

VIRAFERON

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Viraferon?

Viraferon is a medicine containing the active substance interferon alfa-2b. It is available as a powder and solvent to be made up into a solution for injection or infusion, as a ready-to-use solution for injection and as a multidose pen for injection. These contain from 1 to 50 million IU (international units) per millilitre.

What is Viraferon used for?

Viraferon is used for the treatment of:

- chronic (long-term) hepatitis B (a disease of the liver due to an infection by the hepatitis B virus) in adults;
- chronic hepatitis C (a disease of the liver due to an infection by the hepatitis C virus). In adults Viraferon can be used on its own but is best used in combination with ribavirin (an antiviral medicine). In children it is used with ribavirin.

The medicine can only be obtained with a prescription.

How is Viraferon used?

Treatment with Viraferon should be initiated by a doctor who has experience in the management of the disease it is being used for. Viraferon is given three times per week (every other day) by subcutaneous injection (under the skin). The dose and duration of treatment depend on the disease being treated and the response of the patient, with doses ranging from 3 to 10 million IU per square metre of body surface area. For more information, see the Package Leaflet.
Viraferon has to be stored in a refrigerator (2°C-8°C).

How does Viraferon work?

The active substance in Viraferon, interferon alfa-2b, belongs to the group ‘interferons’. Interferons are natural substances produced by the body to help it fight against attacks such as infections caused by viruses. The exact way alpha interferons work in viral diseases is not fully understood, but it is thought that they act as immunomodulators (substances that modify how the immune system, the body’s defence system, works). Alpha interferons may also block the multiplication of viruses.
The interferon alfa-2b in Viraferon is produced by a method known as ‘recombinant DNA technology’: the interferon alfa-2b is made by a bacterium that has received a gene (DNA), which

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makes it able to produce it. The replacement interferon alfa-2b acts in same way as naturally produced interferon alpha.

How has Viraferon been studied?
Because interferon alfa-2b has been used to treat a number of diseases in the European Union (EU) before, the company that makes Viraferon supplied data from the scientific literature and from studies of its use in children with chronic hepatitis B. The company also supplied information from a number of studies of Viraferon used alone or with ribavirin for the treatment of chronic hepatitis C. These included a total of 2,552 treatment-naïve patients (who had not been treated before) and a total of 345 patients whose disease had relapsed (returned) after previous treatment with interferon. The use of Viraferon in combination with ribavirin has also been studied in 118 hepatitis C treatment-naïve children aged between three and 16 years. The main measure of effectiveness was response rates.

What benefit has Viraferon shown during the studies?
The studies showed that Viraferon is effective in the diseases for which it can be used. Viraferon was also shown to have a benefit in children with chronic hepatitis B. Viraferon, with or without ribavirin, was shown to be effective in treating hepatitis C in both treatment-naïve and relapsed adults. It was also effective in children when used with ribavirin, with 46% of the children having responded to treatment at the six-month follow up visit following a year's treatment.

What is the risk associated with Viraferon?
The most common side effects with Viraferon in adults (seen in more than 1 patient in 10) are leucopenia (low white blood cell counts), anorexia (loss of appetite), depression, insomnia (difficulty sleeping), anxiety, agitation, nervousness, dizziness, headache, impaired concentration, dry mouth, blurred vision, nausea (feeling sick) or vomiting, abdominal (tummy) pain, diarrhoea, stomatitis (inflammation of the lining of the mouth), dyspepsia (indigestion), alopecia (hair loss), increased sweating, myalgia (muscle pain), arthralgia (joint pain), musculoskeletal pain (pain in the muscles and bones), inflammation at the site of the injection, fatigue (tiredness), rigors (shaking chills), fever, flu-like symptoms, asthenia (weakness), irritability, chest pain, malaise (feeling unwell) and weight loss. Similar side effects have been seen in children receiving Viraferon, as well as inhibition of growth. For the full list of all side effects reported with Viraferon, see the Package Leaflet.
Viraferon should not be used in people who may be hypersensitive (allergic) to interferon alfa-2b or any of the other ingredients. Viraferon should not be used in:

- patients with a history of severe heart disease,
- patients with severe kidney or liver disease including that caused by cancer,
- patients with epilepsy or other central nervous system problems,
- patients with thyroid disease unless it is controlled,
- hepatitis patients who have liver cirrhosis (scarring) that is causing symptoms or who have recently received medicines that affect the immune system,
- patients with a history of certain disorders of the immune system, or who have had an organ transplant and are taking medicines that suppress the immune system,
- children and adolescents with a history of severe mental illness, particularly severe depression, suicidal thoughts or suicide attempts.

For a list of all restrictions with Viraferon, see the Package Leaflet.
Because Viraferon can be associated with side effects such as depression, patients must be closely monitored during treatment.

Why has Viraferon been approved?
The Committee for Medicinal Products for Human Use (CHMP) decided that Viraferon's benefits are greater than its risks for the treatment of chronic hepatitis B and C. The Committee recommended that Viraferon be given marketing authorisation.

Other information about Viraferon:
The European Commission granted a marketing authorisation valid throughout the EU for Viraferon to SP Europe on 9 March 2000. The marketing authorisation was renewed on 9 March 2005.

The full EPAR for Viraferon is available here.

This summary was last updated in 02-2008.