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EPAR summary for the public

IntronA

interferon alfa 2b

This is a summary of the European public assessment report (EPAR) for IntronA. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for IntronA.

What is IntronA?

IntronA is a medicine that contains the active substance interferon alfa-2b. It is available as a powder and solvent that are made up into a solution for injection or infusion (drip into a vein), and as a ready-to-use solution for injection in a vial or in a multidose pen. These contain between 1 and 50 million international units (IU) per millilitre.

What is IntronA used for?

IntronA is used for the treatment of the following diseases:

- long-term hepatitis B (a disease of the liver due to infection with the hepatitis B virus) in adults (aged 18 years and older);
- long-term hepatitis C (a disease of the liver due to infection with the hepatitis C virus) in patients aged three years and older. It is usually used in combination with ribavirin (an antiviral medicine);
- hairy cell leukaemia (a cancer of the white blood cells);
- chronic myelogenous leukaemia (CML, a cancer of the white blood cells) in adults. IntronA can be used in combination with cytarabine (an anticancer medicine) in the first year;
- multiple myeloma (a cancer of the bone marrow). IntronA is used to maintain anticancer effects in patients who have responded to previous treatment with anticancer medicines;

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- follicular lymphoma (a cancer of the lymph tissue). IntronA is used as an add-on to anticancer treatments;
- carcinoid tumour (a tumour of the endocrine system that produces hormones);
- malignant melanoma (a type of skin cancer affecting cells called melanocytes). IntronA is used after surgery in patients whose melanoma could come back.

The medicine can only be obtained with a prescription.

How is IntronA used?

Treatment with IntronA should be started by a doctor who has experience in the management of the disease it is being used for. IntronA is generally given three times per week but the injection can be given more frequently in CML and melanoma. It is generally given by injection under the skin, but in melanoma it can also be given by infusion. The dose and duration of treatment depend on the disease being treated and the response of the patient, with doses ranging from 2 to 20 million IU per square metre of body surface area (calculated using the patient's height and weight). Patients can inject themselves once they have been trained appropriately. For more information, see the package leaflet.

How does IntronA work?

The active substance in IntronA, 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 that they work in cancer and viral diseases is not fully understood, but it is thought that they act as immunomodulators (substances that modify how the immune system works). They may also block the multiplication of viruses.

Interferon alfa-2b has been available in the European Union (EU) for the treatment of various diseases for a number of years. The interferon alfa-2b in IntronA is produced by a method known as 'recombinant DNA technology': it is made by a bacterium that has received a gene (DNA), which makes it able to produce interferon alfa-2b. The replacement interferon alfa-2b acts in same way as naturally produced interferon alpha.

How has IntronA been studied?

Because interferon alfa-2b has been used in the EU for a number of years, the company presented the results of studies from the published literature, as well as from studies of its use with cytarabine in CML and studies of IntronA used alone (in adults) or with ribavirin (in patients from three years of age) for the treatment of long-term hepatitis C. The main measures of effectiveness were the number of patients who responded to treatment in the hepatitis studies and how long the patients survived in the cancer studies.

What benefit has IntronA shown during the studies?

The studies showed that IntronA is effective in the diseases for which it can be used. In CML, more patients who received IntronA with cytarabine were still alive after three years than patients who only received IntronA. IntronA was also shown to be effective in treating hepatitis C in adults when it was used with or without ribavirin, and in younger patients when used with ribavirin.

What is the risk associated with IntronA?

In adults, the most common side effects with IntronA used with or without ribavirin (seen in more than 1 patient in 10) are pharyngitis (sore throat), viral infection, leucopenia (low white blood cell counts), loss of appetite, depression, insomnia (difficulty sleeping), anxiety, emotional lability (mood swings), agitation, nervousness, dizziness, headache, impaired concentration, dry mouth, blurred vision, dyspnoea (difficulty breathing), coughing, nausea (feeling sick) or vomiting, abdominal pain (stomach ache), diarrhoea, stomatitis (inflammation of the lining of the mouth), dyspepsia (heartburn), alopecia (hair loss), pruritus (itching), dry skin, rash, increased sweating, myalgia (muscle pain), arthralgia (joint pain), musculoskeletal pain (pain in the muscles and bones), reactions at the site of the injection including inflammation, fatigue (tiredness), rigors (shaking chills), pyrexia (fever), flu-like symptoms, asthenia (weakness), irritability, chest pain, malaise (feeling unwell) and weight loss. In children and adolescents receiving IntronA in combination with ribavirin, side effects were similar to adults, although anaemia (low red blood cell counts), neutropenia (low levels of neutrophils, a type of white blood cell), hypothyroidism (underactive thyroid gland) and reduced growth were also seen in more than 1 patient in 10. For the full list of all side effects reported with IntronA, see the Package Leaflet.

IntronA should not be used in people who may be hypersensitive (allergic) to interferon alfa 2b or any of the other ingredients. IntronA must not be used in patients with severe kidney or liver disease, epilepsy or other central nervous system problems, or thyroid disease that is not controlled. It must not be used in patients who have had severe heart disease or certain immune system disorders, in patients who are taking medicines that suppress the immune system, in hepatitis patients who have liver cirrhosis (scarring) that is causing symptoms or who have recently received medicines that affect the immune system, or in children or adolescents with a history of severe mental illness, particularly severe depression, thoughts about committing suicide or suicide attempts. For a list of all restrictions with IntronA, see the package leaflet.

Because IntronA is linked to side effects such as depression, patients must be closely monitored during treatment. IntronA in combination with ribavirin is also linked to weight loss and reduced growth in children and adolescents. Doctors should take this risk into account when deciding whether to treat a patient before adulthood.

Why has IntronA been approved?

The Committee for Medicinal Products for Human Use (CHMP) decided that IntronA's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about IntronA

The European Commission granted a marketing authorisation valid throughout the European Union for IntronA on 9 March 2000. The marketing authorisation is valid for an unlimited period.

The full EPAR for IntronA can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with IntronA, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 12-2011.