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EPAR summary for the public

Extavia

interferon beta-1b

This is a summary of the European public assessment report (EPAR) for Extavia. 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 Extavia.

What is Extavia?

Extavia is a powder and solvent that are made up into a solution for injection. It contains 250 micrograms (8 million international units - MIU) per millilitre of the active substance interferon beta-1b.

This medicine is the same as Betaferon, which is already authorised in the European Union (EU). The company that makes Betaferon has agreed that its scientific data can be used for Extavia.

What is Extavia used for?

Extavia is used to treat adult patients who have multiple sclerosis (MS). MS is a disease of the nerves, in which inflammation destroys the protective sheath around the nerves. This is called 'demyelination'. Extavia is used in patients:

- who have experienced the signs of MS for the first time, and these are severe enough to justify treatment with injected corticosteroids (anti-inflammatory medicines). It is used when the patient is considered to be at high risk of developing MS. Before using Extavia, doctors need to exclude other causes for the symptoms.
- who have MS of the type known as 'relapsing-remitting', when the patient has attacks (relapses) within periods with no symptoms (remissions), and with at least two relapses within the last two years.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

- who have secondary progressive MS (the type of MS that comes after relapsing-remitting MS), when their disease is active.

The medicine can only be obtained with a prescription.

How is Extavia used?

Extavia treatment should be started by a doctor who has experience in the treatment of MS. The treatment should start with 62.5 micrograms (a quarter of the dose) every other day, increasing progressively over 19 days to reach the recommended dose of 250 micrograms (8 MIU) given every other day. Extavia is given by an injection under the skin. The patients can inject Extavia themselves, provided that they have been trained. Extavia treatment should be stopped in patients who fail to respond.

How does Extavia work?

The active substance in Extavia, interferon beta-1b, belongs to a group of medicines known as '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 Extavia works in MS is not yet known but beta-interferon seems to calm down the immune system (the body's natural defences) and prevents the relapses of MS.

Interferon beta-1b is produced by a method known as 'recombinant DNA technology'. The interferon beta-1b is made by a bacterium that has received a gene (DNA), which makes it able to produce it. The replacement interferon beta-1b acts in the same way as naturally produced interferon beta.

How has Extavia been studied?

Extavia was studied over a two year period in 338 patients with relapsing remitting MS who were able to walk unaided, where its effectiveness was compared with placebo (a dummy treatment). The main measure of effectiveness was the reduction in the number of relapses.

Extavia has also been studied in 1,657 patients in two studies of secondary progressive MS patients who were able to walk, where it was compared with placebo. The main measure of effectiveness was the delay to progression of disability.

The study of Extavia in patients with a single demyelinating event involved 487 patients, who received either Extavia or placebo for two years. The study measured the time it took for a patient to develop clinically defined MS.

What benefit has Extavia shown during the studies?

In patients with relapsing remitting MS, Extavia was more effective than placebo in reducing the number of annual relapses: patients receiving the medicine had on average 0.84 relapses a year, when patients on placebo had 1.27 relapses.

One of the two studies in patients with secondary progressive MS showed a significant delay in the time to disability progression (31% risk reduction due to Extavia) and in the time to becoming wheelchair bound (39%). In the second trial, no delay in the time to disability progression was seen. In both trials, Extavia showed a reduction in the number (30%) of clinical relapses.

In the study of patients with a single demyelinating event, Extavia was shown to reduce the risk of developing clinically defined MS: 28% of the patients who received Extavia developed MS, compared with 45% of those who received placebo.

What is the risk associated with Extavia?

The most frequent side effects with Extavia are flu-like symptoms (including fever, chills, arthralgia (joint pain), malaise (feeling unwell), sweating, headache and myalgia (muscle pain)) and reactions at the site of injection. Side effects are common at the beginning of treatment but usually decrease with further treatment. For the full list of all side effects reported with Extavia, see the package leaflet.

Extavia must not be used in people who have a history of hypersensitivity (allergy) to natural or recombinant interferon beta, human albumin or any of the other ingredients. Extavia treatment must not be started during pregnancy. If a woman becomes pregnant while taking the medicine, she should consult her doctor. Extavia must not be used in patients who are currently suffering from severe depression and/or have thoughts of suicide. Extavia must not be used in patients who have decompensated liver disease (when the liver does not function normally).

Why has Extavia been approved?

The CHMP decided that Extavia's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Extavia

The European Commission granted a marketing authorisation valid throughout the European Union for Extavia on 20 May 2008.

The full EPAR for Extavia 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 Extavia, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist..

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