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Biopoin
epoetin theta

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 for the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Biopoin?
Biopoin is a solution for injection. It is available in pre-filled syringes containing between 1,000 and 30,000 international units (IU) of the active substance, epoetin theta.

What is Biopoin used for?
Biopoin is used to treat anaemia (low levels of red blood cells or haemoglobin) that is causing symptoms. It is used in adults with chronic renal failure (long-term, progressive decrease in the ability of the kidneys to work properly) and in adults with non-myeloid cancer (cancer not originating in the bone marrow) who are receiving chemotherapy (medicines to treat cancer).
The medicine can only be obtained with a prescription.

How is Biopoin used?
Biopoin treatment should be started by a doctor experienced in treating symptomatic anaemia in patients with chronic renal failure and non-myeloid cancer.
For patients with kidney failure, in the 'correction phase', the initial recommended dose, given three times a week, is 20 IU per kilogram body weight for injections under the skin or 40 IU per kg body weight for injections into a vein. These doses may be doubled after four weeks if the improvement is not enough and may be increased further at monthly intervals by a quarter of the previous dose until the right level of haemoglobin (the protein found in red blood cells that carries oxygen around the body) is achieved. When the anaemia has been corrected, the dose in the 'maintenance phase' should be adjusted to maintain the right level of haemoglobin. The weekly dose of Biopoin should not at any time be more than 700 IU per kg body weight.
For patients with cancer, injections should be given under the skin. The initial recommended dose is 20,000 IU once a week for all patients irrespective of their body weight. This dose may be doubled after four weeks if the haemoglobin has not increased by at least 1 g/dl and can, if needed, be increased further to 60,000 IU after four additional weeks. The weekly dose of Biopoin should not be more than 60,000 IU. Patients with cancer should continue to receive treatment for up to four weeks after they stop receiving chemotherapy.
Patients who receive Biopoin by injection under the skin may inject themselves once they have been trained appropriately. For full details, see the Package Leaflet.

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How does Biopoin work?
The active substance in Biopoin, epoetin theta, is a copy of a human hormone called erythropoietin that stimulates the production of red blood cells from the bone marrow. Erythropoietin is produced by the kidneys. In patients receiving chemotherapy or with kidney problems, anaemia can be caused by a lack of erythropoietin, or by the body not responding enough to the erythropoietin it has naturally. The epoetin theta in Biopoin works in the body in the same way as the natural hormone to stimulate red blood cell production. It is produced by a method known as 'recombinant DNA technology': it is made by a cell that has received a gene (DNA), which makes it able to produce epoetin theta.

How has Biopoin been studied?
The effects of Biopoin were first tested in experimental models before being studied in humans. There were four main studies in 842 chronic renal failure patients and three main studies in 586 non-myeloid cancer patients receiving chemotherapy.
In the four renal failure studies, patients were given either Biopoin (under the skin or into a vein) or epoetin beta (another erythropoietin-like medicine used for anaemia). The main measure of effectiveness in two of these studies was based on whether increasing the dose of Biopoin from 20 or 40 IU per kg body weight to 120 IU per kg body weight led to improvements in haemoglobin levels during the correction phase. The other two studies compared Biopoin with epoetin beta during the maintenance phase. The main measure of effectiveness was the average change in haemoglobin levels from 15 to 26 weeks after treatment.
In the cancer studies, the main measure of effectiveness was the number of patients receiving either Biopoin or placebo (a dummy treatment) with an increase in haemoglobin of 2 g/dl over 12 or 16 weeks.

What benefit has Biopoin shown during the studies?
Biopoin was effective at treating anaemia in patients with chronic renal failure and patients with non-myeloid cancer who were receiving chemotherapy.
In chronic renal failure patients, the correction phase showed that increasing the starting dose of Biopoin leads to improvements in haemoglobin levels. Average weekly increases in haemoglobin were 0.73 and 0.58 g/dl in patients receiving the higher dose of Biopoin compared with 0.20 and 0.26 g/dl in patients receiving the lower dose of Biopoin. The other two renal failure studies showed that during the maintenance stage the change in haemoglobin levels was similar in patients receiving Biopoin and patients receiving epoetin beta.
In the cancer studies, between 64 and 73% of patients who received Biopoin had an increase in haemoglobin of 2 g/dl compared with between 20 and 26% of patients who were given placebo.

What is the risk associated with Biopoin?
The most common side effects with Biopoin (seen in between 1 and 10 patients in 100) are shunt thrombosis (clots that can form in blood vessels of patients on dialysis, a blood clearance technique), headache, hypertension (high blood pressure), hypertensive crisis (sudden, dangerously high blood pressure), skin reactions, arthralgia (joint pain) and influenza (flu)-like illness. For the full list of all side effects reported with Biopoin, see the Package Leaflet.
Biopoin should not be used in people who may be hypersensitive (allergic) to epoetin theta, to any other epoetins or substances derived from them, or to any of the other ingredients of Biopoin. It must not be used in patients with uncontrolled hypertension.
Because of the risk of high blood pressure, special care should be taken to monitor and control the patient's blood pressure to avoid complications such as a hypertensive crisis.

Why has Biopoin been approved?
The Committee for Medicinal Products for Human Use (CHMP) decided that Biopoin's benefits are greater than its risks for the treatment of symptomatic anaemia in adults with chronic renal failure and adults with non-myeloid cancers who are receiving chemotherapy. The Committee recommended that Biopoin be given marketing authorisation.

Other information about Biopoin:
The European Commission granted a marketing authorisation valid throughout the European Union for Biopoin to CT Arzneimittel GmbH on 23 October 2009.

The full EPAR for Biopoin can be found here.

This summary was last updated in 10-2009.