European Medicines Agency

EMEA/H/C/372

# EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

## DYNEPO

## 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 Dynepo?
Dynepo is a solution for injection in pre-filled syringe. It is available in strengths from 2,000 IU/ml to 20,000 IU/ml. Dynepo contains the active ingredient epoetin delta.

### What is Dynepo used for?
Dynepo is used to treat anaemia (fewer than normal red blood cells in the blood) in adult patients with chronic renal failure (long-term kidney disease). It may be used in patients on dialysis (a blood clearance technique) or not on dialysis.
The medicine can only be obtained with a prescription.

### How is Dynepo used?
A doctor who has experience in the care of renal failure patients should start any treatment with Dynepo. Dynepo can be given intravenously (injection into a vein) or subcutaneously (injection under the skin). The starting doses are 50 IU/kg three times a week if given intravenously, and twice a week if given subcutaneously. Doses are adjusted depending on the response.

### How does Dynepo work?
A hormone called erythropoietin stimulates the production of red blood cells from the bone marrow. Epoetin delta, the active ingredient of Dynepo, is a copy of the human hormone, produced by a method known as 'genetic engineering': the enzyme is made by a cell in which the gene (the code) for the enzyme is activated so that the cell makes more of the enzyme and it can then be extracted and used in Dynepo. In patients with long-term kidney failure, a cause of their anaemia can be a lack of erythropoietin. Dynepo works by stimulating production of red blood cells in the same way as erythropoietin.

### How has Dynepo been studied?
The effectiveness of Dynepo to treat anaemia has been studied in a total of 1308 patients with chronic renal failure, including two main clinical studies. In one of these, Dynepo given intravenously was compared with epoetin alfa (a similar type of drug). In the other study, three different dosing schedules of subcutaneous Dynepo were compared. The main measure of effectiveness in the clinical studies was whether Dynepo increased haemoglobin levels (the protein found in red blood cells that carries oxygen around the body).

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**What benefit has Dynepo shown during the studies?**
Dynepo was as effective as epoetin alfa at increasing haemoglobin levels in patients. The effectiveness was the same if it was administered intravenously or subcutaneously.

**What is the risk associated with Dynepo?**
The most common side effects are hypertension (raised blood pressure), headache, and, for patients on dialysis, problems with the dialysis tubes. For the full description of the side effects reported with Dynepo, please see the Package Leaflet.
Dynepo should not be used in people who may be hypersensitive (allergic) to epoetin delta or any of the other ingredients, and in patients who have uncontrolled high blood pressure. Allergic reactions have occasionally been seen, so it is recommended that the first dose of Dynepo be given under medical supervision.

**Why has Dynepo been approved?**
The Committee for Medicinal products for Human Use (CHMP) decided that Dynepo's benefits are greater than its risks for the treatment of anaemia in patients with chronic renal failure. They recommended that Dynepo be given marketing authorisation.

**Other information about Dynepo:**
The European Commission granted a marketing authorisation valid throughout the European Union, for Dynepo to Shire Pharmaceutical Contracts Ltd on 18 March 2002. The marketing authorisation was renewed on 18 March 2007.

The full EPAR for Dynepo is available here.

**This summary was last updated in 03-2007.**