EMA/183641/2011
EMEA/H/C/000293

EPAR summary for the public

Osigraft

eptotermin alfa

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

What is Osigraft?

Osigraft is a powder to be made up into a suspension for implantation. It contains the active substance eptotermin alfa.

What is Osigraft used for?

Osigraft is used to repair fractures of the tibia (shin bone) that have not healed after at least nine months. It is used in patients who have previously had an autograft (a bone graft taken from their own bone, usually the hip) that has failed or when such a graft is not possible. It is used in skeletally mature patients (who have stopped growing).

The medicine can only be obtained with a prescription.

How is Osigraft used?

Osigraft should be used by a qualified surgeon. Immediately before use, Osigraft is mixed with 2 to 3 ml of sodium chloride solution to make up a suspension that has the consistency of wet sand. This mixture is then placed by the surgeon directly at the fracture site in contact with the prepared broken bone ends. The surrounding soft tissues, such as muscle and skin, are then closed around the implant. Generally, one vial is sufficient, but a further vial can be used if necessary.

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

How does Osigraft work?

The active substance in Osigraft, eptotermin alfa, acts on the bone structure. It is a copy of a protein called osteogenic protein 1, also known as bone morphogenetic protein 7 (BMP-7), that is produced naturally by the body and which helps the formation of new bone tissue. When implanted, eptotermin alfa stimulates the formation of new bone, helping to repair the broken bone. Eptotermin alfa is produced by a method known as 'recombinant DNA technology': it is made by cells that have received a gene (DNA), which makes them able to produce it. The replacement eptotermin alfa acts in same way as naturally produced BMP-7.

How has Osigraft been studied?

The main study of Osigraft was carried out in 122 patients with unhealed tibial fractures who were treated either with the medicine or with an autograft. The main measure of effectiveness, which was assessed after nine months, was whether the broken bone had healed. This was detected by looking at signs of repair of the fracture on an X-ray, whether the patient had any pain and was able to bear weight on the tibia, and whether there was any need for further treatment of the fractured tibia.

What benefit has Osigraft shown during the studies?

Osigraft was at least as effective as bone autograft, the standard treatment. After nine months, 81% of the patients receiving Osigraft had responded to treatment (less pain and more weight bearing), compared with 77% of the patients treated with an autograft.

What is the risk associated with Osigraft?

The most common side effects with Osigraft (seen in between 1 and 10 patients in 100) are erythema (redness), tenderness, swelling over the implant site, heterotopic ossification (development of bone in abnormal areas) or myositis ossificans (abnormal bone growth in the muscle), and the formation of antibodies against eptotermin alfa. For the full list of all side effects reported with Osigraft, see the package leaflet.

Osigraft should not be used in people who may be hypersensitive (allergic) to eptotermin alfa or to collagen. Osigraft must also not be used by the following groups of patients:

- skeletally immature (still growing);
- under 18 years old;
- with an autoimmune disease (where the immune system attacks parts of the body);
- with an active infection at the surgery site or another serious infection;
- without enough skin or blood supply at the fracture site;
- where the fracture is disease-related (such as metabolic bone disease or cancer);
- with a tumour near the fracture;
- receiving chemotherapy, radiation treatment or immunosuppression.

Why has Osigraft been approved?

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

Other information about Osigraft

The European Commission granted a marketing authorisation valid throughout the European Union for Osigraft to Howmedica International S. de R. L. on 17 May 2001. The marketing authorisation is valid for an unlimited period.

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

This summary was last updated in 03-2011.