European Medicines Agency

EMEA/H/C/104

EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

REVASC

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 Revasc?

Revasc is a powder and solvent in a vial, which is made up into a solution for injection.
Revasc contains the active substance desirudin.

What is Revasc used for?

Revasc is used in adult patients to prevent blood clotting after hip or knee replacement surgery.
Revasc is intended for short-term use.
The medicine can only be obtained with a prescription.

How is Revasc used?

Revasc is intended to be given subcutaneously (under the skin), preferably in the abdomen (the tummy). A doctor who has experience in coagulation (clotting) disorders should start treatment with Revasc. The recommended dose of Revasc is 15 mg twice daily. The first injection should be started 5 to 15 minutes before surgery but after any anaesthesia. Revasc is then given twice daily for 9 and up to a maximum of 12 days, or until the patient is able to walk, whichever occurs first. In patients who have liver or kidney problems, the doctor will monitor blood clotting to see if the dosages may need to be adjusted.

How does Revasc work?

Blood clotting can be a problem when blood flow is disturbed in any way. Revasc is an anticoagulant; it prevents the blood from coagulating (clotting). Desirudin, the active substance in Revasc, is nearly identical to hirudin, the anticoagulant substance produced by leeches. Desirudin is produced by a method known as 'recombinant DNA technology': it is made by a yeast that has received a gene (DNA), which makes it able to produce the substance. It specifically blocks one of the substances involved in the clotting process, thrombin. Thrombin is central to the complete process of blood clotting. By using Revasc during and after hip or knee surgery, the risk of a blood clot forming in the blood vessels of the legs (deep vein thrombosis) is greatly reduced.

How has Revasc been studied?

The effectiveness of Revasc as an anticoagulant has been studied in four studies involving 1,621 patients who received Revasc. Revasc was compared with unfractionated heparin or enoxaparin (other anticoagulants). The main measures were the overall rate of thrombotic events (blood clots causing

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problems) and the rate of deep vein thrombosis (the formation of a blood clot in one of the deep veins of the body, usually in the leg).

What benefit has Revasc shown during the studies?
The studies showed that desirudin was more effective than both comparator medicines in the prevention of deep vein thrombosis after hip replacement surgery.

What is the risk associated with Revasc?
The most common side effects with Revasc (seen in between 1 and 10 patients in 100) are anaemia (low red blood cell counts), nausea (feeling sick), wound secretion (oozing of fluid from wounds), hypotension (low blood pressure), deep thrombophlebitis (inflammation of deep veins that can be caused by a blood clot), fever, injection site mass (lumps at the site of injection), haematomas (collections of blood), oedema (swelling) in legs, and non-fatal allergic reactions. As with other anticoagulants, a common side effect of Revasc is bleeding. Some patients can have an allergic shock when they receive Revasc again, and doctors should be very careful when re-exposing a patient to the medicine or to another hirudin analogue. For the full description of all side effects reported with Revasc, see the Package Leaflet.
Revasc should not be used in people who may be hypersensitive (allergic) to desirudin or any of the other ingredients, who are pregnant, who have had recent bleeding, who have severe high blood pressure or severe liver or kidney problems, or who have a heart infection. For the full list of restrictions, see the Package Leaflet.

Why has Revasc been approved?
The Committee for Medicinal products for Human Use (CHMP) decided that Revasc's benefits are greater than its risks to prevent deep vein thrombosis in patients undergoing hip or knee replacement. The Committee recommended that Revasc be given marketing authorisation.

Other information about Revasc:
The European Commission granted a marketing authorisation valid throughout the European Union for Revasc to Canyon Pharmaceuticals Limited on 9 July 1997. The marketing authorisation was renewed on 9 July 2002 and on 9 July 2007.

The full EPAR for Revasc can be found here.

This summary was last updated in 07-2007.