

Summary Public Assessment Report

Bivalirudin Reig Jofre (bivalirudin)

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Bivalirudin Reig Jofre
(bivalirudin)

Powder for concentrate for solution for injection or infusion, 250 mg

This is a summary of the public assessment report (PAR) for Bivalirudin Reig Jofre. It explains how Bivalirudin Reig Jofre was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Bivalirudin Reig Jofre.

For practical information about using Bivalirudin Reig Jofre, patients should read the package leaflet or contact their doctor or pharmacist.

What is Bivalirudin Reig Jofre and what is it used for?

Bivalirudin Reig Jofre is a 'generic medicine'. This means that Bivalirudin Reig Jofre is similar to a 'reference medicine' already authorised in the European Union (EU) called Angiox.

Bivalirudin Reig Jofre contains a substance called bivalirudin which is an antithrombotic medicine.

Bivalirudin Reig Jofre is used to treat patients:

- with chest pain due to heart disease (acute coronary syndrome - ACS)
- who are having surgery to treat blockages in their blood vessels (angioplasty and/or percutaneous coronary intervention - PCI).

How does Bivalirudin Reig Jofre work?

Bivalirudin Reig Jofre contains a substance called bivalirudin which is an antithrombotic medicine. Antithrombotics are medicines which prevent the formation of blood clots (thrombosis).

How is Bivalirudin Reig Jofre used?

The pharmaceutical form of Bivalirudin Reig Jofre is powder for concentrate for solution for injection or infusion and is used for injection, followed by infusion (drip), into a vein (never into a muscle).

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Bivalirudin Reig Jofre have been shown in studies?

No additional studies were needed as Bivalirudin Reig Jofre is a generic medicine that is given by infusion/intravenous injection and contains the same active substance as the reference medicine, Angiox.

What are the possible side effects of Bivalirudin Reig Jofre?

Because Bivalirudin Reig Jofre is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine. For the full list of restrictions, see the package leaflet.

Why is Bivalirudin Reig Jofre approved?

It was concluded that, in accordance with EU requirements, Bivalirudin Reig Jofre has been shown to have comparable quality and to be similar to the reference medicine Angiox. Therefore, the Medical Products Agency in Sweden decided that, as for Angiox, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Bivalirudin Reig Jofre?

A risk management plan has been developed to ensure that Bivalirudin Reig Jofre is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Bivalirudin Reig Jofre, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

As the originator, Angiox, has additional risk minimisation measures in the form of educational material, and it follows that the generic product also should provide this type of material, additional risk minimisation measures have now been included in the updated risk management plan.

Other information about Bivalirudin Reig Jofre

The marketing authorisation for Bivalirudin Reig Jofre was granted on 2016-01-28 in Sweden.

The full PAR for Bivalirudin Reig Jofre can be found on the following website: <http://mri.medagencies.org/Human/>. For more information about treatment with Bivalirudin Reig Jofre please read the [package leaflet](#) or contact your doctor or pharmacist.

This summary was last updated in 2016-01.