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## EPAR summary for the public

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# Angiox

## bivalirudin

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

### What is Angiox?

Angiox is a medicine that contains the active substance bivalirudin. It is available as a powder that is made up into a solution for injection or infusion (drip) into a vein.

### What is Angiox used for?

Angiox is used to prevent blood clots in adults who are undergoing percutaneous coronary intervention (PCI), a non-surgical procedure used to unblock the heart's blood vessels. This includes patients who are having myocardial infarction (a heart attack) with 'ST segment elevation' (an abnormal reading on the electrocardiogram or ECG).

Angiox is also used to treat adults with unstable angina (a type of chest pain that varies in severity) or myocardial infarction without ST segment elevation, who are waiting for further treatment such as PCI, a heart bypass or using other medicines.

Angiox is used together with aspirin and clopidogrel (other medicines that help to prevent blood clots).

The medicine can only be obtained with a prescription.

### How is Angiox used?

Angiox should be given by a doctor who has experience in the emergency care of patients with heart problems or in carrying out procedures on the heart.



The dose of Angiox and the duration of treatment depend on why it is being used. The first dose is given by injection into a vein, which must be followed immediately by an infusion for at least the duration of the procedure. In patients being treated for angina or myocardial infarction without ST segment elevation, the duration of the infusion depends on how the patient is going to be treated. The rate of the infusion needs to be reduced in patients with moderate kidney problems who are undergoing PCI.

For more information, see the summary of product characteristics (also part of the EPAR).

## **How does Angiox work?**

Blood clotting can be a problem when blood clots develop inside blood vessels and restrict the blood flow to major organs such as the heart and the brain. Angiox is an anticoagulant, which means that it prevents the blood from clotting. The active substance in Angiox, bivalirudin, is a synthetic substance originally derived from hirudin, the anticoagulant substance produced by leeches. It specifically blocks one of the substances involved in the clotting process called thrombin. Thrombin is central to the processes involved in blood clotting. Using Angiox greatly reduces the risk of a blood clot forming. This can improve the effectiveness of PCI and help to maintain the flow of blood to the heart in patients with angina or myocardial infarction.

## **How has Angiox been studied?**

In PCI, Angiox has been compared with another type of anticoagulant, a heparin, in two studies involving a total of almost 10,000 adults. Heparin was given in combination with a glycoprotein IIb/IIIa inhibitor (GPI, another type of medicine that helps to prevent blood clots) and some patients receiving Angiox were also given a GPI where appropriate. Almost 4,000 of the patients were having PCI to treat myocardial infarction with ST segment elevation.

In patients with unstable angina or myocardial infarction without ST segment elevation waiting for further treatment, the main study involved almost 14,000 adults and compared Angiox taken alone or with a GPI, with the combination of heparin and a GPI.

In all three studies, the patients also received other medicines to prevent blood clots, such as aspirin and clopidogrel. The main measure of effectiveness was the reduction in the number of patients who had an 'ischaemic event' (a problem caused by reduced blood flow) including death, a heart attack, urgent revascularisation (restoration of blood flow to the heart) or stroke after 30 days. The studies also looked at the number of patients who had major bleeding.

## **What benefit has Angiox shown during the studies?**

In both studies of patients undergoing PCI, Angiox (alone or with a GPI where appropriate) was as effective as heparin in combination with a GPI at preventing new ischaemic events. When used to treat unstable angina or myocardial infarction without ST segment elevation, Angiox, given with or without a GPI, was as effective as the combination of heparin and a GPI in preventing deaths, heart attacks and revascularisations. It was most effective in patients who also took aspirin and clopidogrel. Major bleeding was less common with Angiox alone than with heparin plus GPI.

## **What is the risk associated with Angiox?**

The most common side effect with Angiox (seen in more than 1 patient in 10) is minor bleeding. For the full list of all side effects reported with Angiox, see the package leaflet.

Angiox must not be used in people who are hypersensitive (allergic) to bivalirudin, other hirudins, or any of the other ingredients. It must also not be used in patients who have recently been bleeding, or who have severe high blood pressure, severe kidney problems or a heart infection. For the full list of restrictions, see the package leaflet.

### **Why has Angiox been approved?**

The CHMP concluded that Angiox is an acceptable substitute for heparin during PCI and in the treatment of unstable angina and myocardial infarction. It decided that Angiox's benefits are greater than its risks and recommended that it be given marketing authorisation.

### **What measures are being taken to ensure the safe use of Angiox?**

The company that makes Angiox will provide all doctors who are expected to prescribe the medicine with training and educational materials on how to use it correctly, including dosing instructions.

### **Other information about Angiox**

The European Commission granted a marketing authorisation valid throughout the European Union for Angiox on 20 September 2004.

The full EPAR for Angiox can be found on the Agency's website: [ema.europa.eu/Find medicine/Human medicines/European public assessment reports](http://ema.europa.eu/Find medicine/Human medicines/European public assessment reports). For more information about treatment with Angiox, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 12-2012.