October, 2016

Important Safety Update for Angiomax® (bivalirudin) Powder for Injection

New Safety Information has been added to the CONTRAINDICATIONS, PRECAUTIONS, and DOSAGE AND ADMINISTRATION sections of the Product Information

Dear Health Care Provider:

The Medicines Company Australia Pty Ltd would like to inform you of important new safety information that has been added to the CONTRAINDICATIONS, PRECAUTIONS, and DOSAGE AND ADMINISTRATION sections of the Product Information (PI) for Angiomax® (bivalirudin) Powder for Injection (AUST R 102155).

Angiomax® is indicated for use as an anticoagulant:

- in the treatment of patients with moderate to high risk acute coronary syndromes (ACS) (unstable angina/non-ST segment elevation myocardial infarction (UA/NSTEMI) who are undergoing early invasive management, and
- in patients undergoing percutaneous coronary intervention (PCI).

Angiomax® is intended for use with aspirin.

A P2Y12 antagonist (eg, clopidogrel or ticlopidine) may be used in addition to aspirin.

The new safety information is described below:

CONTRAINDICATIONS

The following information has been added to the CONTRAINDICATIONS section of the PI:

- severe renal impairment (GFR<30 mL/min) and in dialysis-dependent patients.

Please refer to the PI for the full list of CONTRAINDICATIONS.

PRECAUTIONS

The following information has been added to the PRECAUTIONS section of the PI:

Co-administration with platelet inhibitors or anti-coagulants

Combined use of platelet inhibitors or anti-coagulant medicinal products can be expected to increase the risk of bleeding. When Angiomax® is combined with a platelet inhibitor or an anti-coagulant medicine, clinical and biological parameters of haemostasis should be regularly monitored. In patients taking warfarin who are treated with Angiomax®, International Normalised Ratio (INR) monitoring should be considered to ensure that it returns to pre-treatment levels following discontinuation of Angiomax® treatment.

Acute Stent Thrombosis

Acute stent thrombosis (<24 hours) has been observed in patients with ST segment elevation myocardial infarction (STEMI) undergoing primary PCI and has been managed by Target

Vessel Revascularisation (TVR). Patients should remain for at least 24 hours in a facility capable of managing ischemic complications and should be carefully monitored following primary PCI for signs and symptoms consistent with myocardial ischemia.

An increased incidence of acute stent thrombosis has been observed in STEMI patients undergoing primary PCI. The majority of these cases were non-fatal. This increased risk of acute stent thrombosis was observed during the first 4 hours following the end of the procedure.

Effects on Laboratory Tests

In patients receiving warfarin, INR is increased by administration of Angiomax®. Therefore, INR may not be useful for determining the appropriate dose of warfarin. In patients taking warfarin who are treated with Angiomax®, INR monitoring should be considered to ensure that it returns to pre-treatment levels following discontinuation of Angiomax® treatment.

Please refer to the PI for the full list of PRECAUTIONS.

DOSAGE AND ADMINISTRATION

Additional dosage instructions for STEMI patients undergoing primary PCI are included as follows:

PCI

The recommended dosage of Angiomax® for patients undergoing PCI is an IV bolus dose of 0.75 mg/kg immediately followed by an IV infusion at a rate of 1.75 mg/kg/hour for the duration of the procedure, or for up to 4 hours post-PCI, as clinically indicated.

In STEMI patients undergoing primary PCI, Angiomax® infusion at a rate of 1.75 mg/kg/hour should be continued for up to 4 hours post-procedure as clinically necessary.

Please refer to the PI for the DOSAGE AND ADMINISTRATION information.

PRESCRIBER ACTION

The above information has been added to the PI for Angiomax® please review the enclosed PI or the PI available on the TGA's website at www.ebs.tga.gov.au before prescribing to ensure that you have the most up-to-date version

Sincerely,

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The Medicines Company

Enclosure: Angiomax® (bivalirudin) PI (version 9 September 2016)