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Summary of the risk management plan (RMP) for Eptifibatide Accord (eptifibatide)

This is a summary of the risk management plan (RMP) for Eptifibatide Accord, which details the measures to be taken in order to ensure that Eptifibatide Accord is used as safely as possible. For more information on RMP summaries, see here.

This RMP summary should be read in conjunction with the EPAR summary and the product information for Eptifibatide Accord, which can be found on Eptifibatide Accord's EPAR page.

Overview of disease epidemiology

Eptifibatide Accord is a medicine used to prevent heart attacks in patients:

- who have unstable angina (episodes of chest pain caused by poor blood flow to the heart, that occur without an obvious trigger such as exertion)
- or who have already had a non-Q-wave myocardial infarction, a type of heart attack.

A heart attack results from sudden interruption of the flow of oxygen-rich blood to a section of heart muscle and may cause chest pain (angina) and other signs such as changes in the electrical activity of the heart. If blood flow is not restored quickly, this section of heart muscle begins to die (myocardial infarction).

Heart attack is one of the most common causes of mortality worldwide. Over seven million people die every year from heart attack, accounting for 12.8% of all deaths. Heart attacks can be associated with or lead to severe health problems, such as heart failure (when the heart can't pump enough blood to meet the body's needs) and life-threatening arrhythmias (irregular heartbeats).

Summary of treatment benefits

Eptifibatide Accord contains the active substance eptifibatide, which helps to stop cells in the blood called platelets from sticking together (aggregating) to form clots that can block blood supply. Eptifibatide Accord is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union called Integrilin.

Because Eptifibatide Accord is a generic medicine, its benefits and risks are taken as being the same as those of the reference medicine. The company provided data from the published literature on eptifibatide. No additional studies were needed as Eptifibatide Accord is a generic medicine that is given into a vein by injection or infusion (drip), and contains the same active substance as the reference medicine, Integrilin.

Unknowns relating to treatment benefits

There is no information on the effectiveness of eptifibatide in children and adolescents below 18 years of age and such use is not recommended. Studies in patients with reduced liver function as well as in pregnant and breastfeeding women are lacking.

Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Bleeding in patients with moderately reduced kidney function (haemorrhage in moderate renal impairment)	There are few data on the effect of Eptifibatide Accord in patients with renal impairment. In patients with moderate renal impairment (creatinine clearance 30–50 ml/minute) eptifibatide completely stopped platelets from sticking together (100% inhibition) after 24 hours of treatment with a standard dose (2 micrograms/kg/minute).	The product information for Eptifibatide Accord contains advice for healthcare professionals on reducing the infusion dose of the medicine to 1 microgram/kg/minute in patients with moderately reduced kidney function, and on monitoring such patients carefully for bleeding. Before treatment with eptifibatide is started, patients should inform their doctor if they have or have had severe kidney problems, as the medicine may not be suitable for them. If patients notice any bleeding during treatment, they should tell a healthcare professional immediately.
Reduction in the number of platelets in the blood (thrombocyto-penia)	This uncommon side effect may affect up to 1 in 100 people.	Patients must not use Eptifibatide Accord if they have or have had difficulty with blood clotting or a low blood platelet count. If patients notice any bleeding during treatment, they should tell a healthcare professional immediately.

Important potential risks

Not applicable

Missing information

Not applicable

Summary of risk minimisation measures by safety concern

All medicines have a summary of product characteristics (SmPC) which provides physicians, pharmacists and other healthcare professionals with details on how to use the medicine, and also describes the risks and recommendations for minimising them. Information for patients is available in lay language in the package leaflet. The measures listed in these documents are known as ‘routine risk minimisation measures’.

The SmPC and the package leaflet are part of the medicine’s product information. The product information for Eptifibatide Accord can be found on Eptifibatide Accord’s EPAR page.

This medicine has no additional risk minimisation measures.

Planned post-authorisation development plan

List of studies in post-authorisation development plan

No studies planned.

Studies which are a condition of the marketing authorisation

Not applicable.

Summary of changes to the risk management plan over time

Major changes to the Risk Management Plan over time

Not applicable.

This summary was last updated in 12-2015.