VI.2 Elements for a public summary

VI.2.1 Overview of disease epidemiology

Eptifibatide is a medicine used to prevent myocardial infarction (heart attacks) in patients, who have unstable angina; episodes of chest pain. Angina can be caused by poor blood flow to the heart, occurring without an obvious trigger. Eptifibatide is also used for patients who have already had a specific type of heart attack called a non-Q-wave myocardial infarction.

A heart attack results from a sudden interruption of the blood flow to the heart muscle, leading to chest pain or other signs such as pain radiating to the arm. If blood flow is not quickly restored, this section of heart muscle begins to die.

Cardiovascular disease (CVD) is one of the most common causes of mortality, accounting for 30% of all deaths worldwide (1). Heart attacks can lead to serious health problems, such as heart failure (when the heart can't pump enough blood to meet the body's needs) and life-threatening irregular heartbeats (arrhythmias).

VI.2.2 Summary of treatment benefits

Eptifibatide ADOH 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 the blood supply.

VI.2.3 Unknowns relating to treatment benefits

Data concerning the effectiveness of eptifibatide in the pediatric population below 18 years of age, or in pregnant and lactating women are missing. Therefore, the use of eptifibatide in these populations is not recommended.

VI.2.4 Summary of safety concerns

Summary of safety concerns – important identified risks

Risk	**What is known**	**Preventability**

Bleeding, particularly in patients with a moderately reduced kidney function (Bleeding including increased risk of haemorrhage in patients with moderate renal impairment)	Eptifibatide is an antithrombotic agent, meaning that blood will clot less due to the inhibition of platelet aggregation. If a patient is wounded during eptifibatide treatment, bleeding will increase. Therefore, all patients must be carefully observed for indications of bleeding. During treatment, there is a higher risk of bleeding at the location of the catheter femoral artery, where the catheter is inserted (in the thigh). Women, elderly, patients with a low body weight or with reduced kidney function (creatinin clearance is 30-50 ml/min) might have an increased risk of bleeding. These patient groups should be closely monitored.	The product information for Eptifibatide ADOH contains advice how these patients should be closely monitored before and after the administration.
Reduction in the number of platelets in the blood (Thrombocytopenia)	As demonstrated in clinical trials, the incidence of thrombocytopenia was low and similar in patients treated with eptifibatide or placebo. Thrombocytopenia has been observed in post-marketing eptifibatide administration. Research suggests an immunemediated mechanism, where the body responds to the class of inhibitors eptifibatide belongs to, namely the GP IIb/IIIa inhibitors.	Platelet count should be monitored in patients before and during the therapy. It is not recommended to administer eptifibatide to patients who experienced previous thrombocytopenia from other GP IIb/IIIa inhibitors.

Summary of safety concerns – important potential risks

No important potential risks were identified.

Summary of safety concerns –Missing information

No missing information was identified.

VI.2.5 Summary of risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in

the form of the package leaflet (PL). The measures in these documents are known as routine risk minimisation measures.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post-authorisation development plan

No post-authorisation studies are planned and therefore this section is not applicable.

VI.2.7 Summary of changes to the risk management plan over time

Not applicable, since this is the first RMP of Eptifibatide ADOH.