VI.2 Elements for a public summary

VI.2.1 Overview of disease epidemiology

Eplerenone is a medicine to help excrete excess body fluid (diuretic) and therefore help with the treatment of heart failure.
Heart failure develops when the heart fails to pump blood required to meet the body's need. Heart failure is a major public health issue, with over 23 million patients affected worldwide, and rising. The lifetime risk of developing heart failure is one in five. In the western countries around 1-2% of the population is affected with this disease. Persons younger than 50 years are hardly ever found to have heart failure, but in those older than 50 years the incidence increases with age. The disease which narrows the blood wall and reduces blood flow to the heart (coronary artery disease), notably increases the chance of developing heart failure; in 7–8 years after heart attack (myocardial infarction) up to 36% of patients will experience heart failure. In general, the mortality following hospitalization for patients with heart failure is 10.4% at 30 days, 22% at 1 year, and 42.3% at 5 years, despite marked improvement in medical and device therapy.

VI.2.2 Summary of treatment benefits

Eplerenone film-coated tablets are used to treat heart failure to prevent worsening and reduce hospitalisations if patients:

1. had a recent heart attack, in combination with other drugs that are used to treat heart failure, or,
2. have persistent, mild symptoms despite the treatment the patient has been receiving so far.

Eplerenone was studied in patients with heart failure after heart attack. In this study, eplerenone reduced the risk of death by 15% compared to no treatment (placebo).
In another study, eplerenone was used along with standard treatment to a patient group of at-least 55 years older and hospitalized after heart failure. The group of patient treated with eplerenone along with standard treatment show fewer deaths compared to the group having only standard treatment.

VI.2.3 Unknowns relating to treatment benefits

Eplerenone has not been studied in children and adolescents and during pregnancy and lactation.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Increased potassium in blood **(Hyperkalaemia)**	Patients with kidney insufficiency and patients with diabetes are more often affected by hyperkalaemia. The risk of hyperkalaemia increases with decreasing kidney function. Combination of eplerenone with some medicines such as potassium supplements, angiotensin converting enzyme (ACE) inhibitor and/or an angiotensin receptor blocker (ARB), cyclosporin and tacrolimus, trimethroprim, should be avoided because it may increase the risk of hyperkalaemia. Hyperkalaemia is a common side effect which may occur between 1 and 10 out of every 100 patients.	Before taking the medicine you should tell your doctor for any history of high levels of potassium in blood (hyperkalemia). Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. The doctor may measure your blood potassium levels before starting eplerenone therapy, within the first week and at one month after the start of treatment or after a change in dose. The dose may be adjusted by the doctor, depending on the potassium levels in blood.
Kidney problems **(Renal impairment)**	Patients with impaired renal function are at high risk for high blood potassium levels. The risk of hyperkalaemia increases with decreasing kidney function. Patients with renal insufficiency may record higher than normal eplerenone blood levels which in turn may render persistent pharmacological effects. Abnormal functioning of kidney and increased levels of creatinine are common side effects which may occur between 1 and 10 out of every 100 patients.	Before taking the medicine tell your doctor for any history of severe kidney disease. Also inform your doctor if you are taking any other medicines.

Important potential risks:
Not applicable

Missing information

Risk	What is known
Use during pregnancy and lactation	There are no adequate data on the use of eplerenone in pregnant women. Caution should be exercised prescribing eplerenone in this patient group. It is unknown if eplerenone is found in human breast milk after being taken by mouth. Because of the unknown potential for adverse effects on the breast fed infant, a decision should be made whether to stop breast-feeding or stop the drug, taking into account the importance of the drug to the mother
Use in children and adolescents	Eplerenone has not been studied in this patient population, thus no dosing instructions can be recommended at this stage. The product should not be employed for paediatric use.

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.

The Summary of Product Characteristics and the Package leaflet for this product can be found at the agency's EPAR page.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

Not applicable. No postauthorisation studies are planned.

VI.2.7 Summary of changes to the Risk Management Plan over time

Not applicable, this is the first Risk management plan.