

RMP section VI.2 Elements for Public Summary

Product: Adrenalin Stragen, 0,1 mg/ml solution for injection in pre-filled syringe

RMP: Version 1.0

DLP: 31-05-2014

MAH: Stragen Nordic A/S

VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Cardiac arrest is the cessation of normal circulation of the blood due to failure of the heart to contract effectively. This constitutes a major health problem, with mortality around 90 %. In Europe, incidence of out-of-hospital cardiopulmonary arrest is 38 per 100 000 population, and incidence of in-hospital cardiac arrest corresponds to 5 per 1 000 patient admissions.

Anaphylaxis is as a serious allergic reaction that is rapid in onset and may cause death. The prevalence of anaphylaxis is estimated to be as high as 2% and appears to be rising, with increase in the number of cases of fatal anaphylaxis. Foods are the most common triggers for anaphylactic reactions, followed by drugs, insect stings, and idiopathic anaphylaxis.

VI.2.2 Summary of treatment benefits

Adrenaline is widely advocated as the initial treatment of choice for anaphylaxis. Current international and local anaphylaxis guidelines unanimously recommend prompt administration of adrenaline as the life-saving first-line medication in any case of anaphylaxis.

Adrenaline is the primary drug administered during cardiopulmonary resuscitation (CPR) to reverse cardiac arrest. Its administration has been advocated during resuscitation of cardiac arrest for decades and forms a component of currently published American Heart Association (AHA) and European Resuscitation Council (ERC) guidelines for adult and paediatric Advanced Life Support (ALS).

VI.2.3 Unknowns relating to treatment benefits

None (well-established use product).

VI.2.4 Summary of safety concerns**Important identified risks**

Risk	What is known	Preventability
Administration error (administration error)	Medication error is a common risk with all injectable products in small container	The presentation in pre-filled syringe form should reduce the risk of medication error with ampoules.
Lack of drug effect (Lack of drug effect)	A lack of drug effect may be observed	None
Tissue damage (Tissue necrosis)	Adrenaline administration may lead to tissue damage (tissue necrosis)	None
Restriction in blood supply to limb tissues (Peripheral ischemia)	Adrenaline administration may lead to restriction in blood supply to limb tissues (Peripheral ischemia)	None

Important potential risks

None

Missing information

None

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

None.

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

Major changes to the Risk Management Plan over time: not applicable.