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RMP section VI.2 Elements for Public Summary

Product: Atropin Stragen, 0,1 mg/ml solution for injection in pre-filled syringe
Atropin Stragen, 0,2 mg/ml solution for injection in pre-filled syringe

RMP: Version 0.3

DLP: 30-05-2015

MAH: Stragen Nordic A/S

VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology (Maximum 150 words per indication)

- Vagal reactions (pre-anaesthetic medication)

Intubation, surgical manipulation of visceral organs or eyes may induce malaise. This may also be observed following the administration of drugs used during anaesthesia, such as suxamethonium, halothane or propofol.

- Bradycardiac conditions in which inhibition of vagus-tone is indicated

  - Cardiopulmonary resuscitation

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.

- Myocardial infarction

Myocardial infarction (or heart attack) happens when blood stops flowing properly to part of the heart and the heart muscle is injured due to not receiving enough oxygen. This constitutes a major health problem, with an overall mortality rate around 30%. Many risk factors are associated with heart attack, such as hypertension, diabetes, physical activity, alcohol use, abnormal lipids, current smoking, abdominal obesity, high risk diet, and psychosocial stress factors. Besides, heart attack more frequently concerns men rather than female.

- Overdose of anticholinesterases, acute poisoning from organophosphorus insecticides and treatment of mushroom poisoning

Overdose of anticholinesterases, acute poisoning from organophosphorus, carbamates or muscarinic mushrooms cause the inhibition of acetylcholinesterase (AChE), leading to the accumulation of acetylcholine (ACh) in the body. This most commonly results from exposure to insecticides or nerve agents. This constitutes a serious safety concern with possibly a fatal outcome: the time of death after single acute exposure may range from less than 5 minutes to nearly 24 hours depending on dose, route, agent, and other factors.

VI.2.2 Summary of treatment benefits

Atropine is a well-established use product and its benefits are widely described in the scientific literature:

- Atropine is commonly used to block the vagal stimulation induced by intubation, surgical manipulation of visceral organs or eyes.
- During cardiopulmonary resuscitation, Atropine is used to block the effects of vagus nerve and thereby increase sinus automaticity, facilitate auriculo-ventricular node conduction and increase heart rate.
- Atropine can be used during treatment of myocardial infarction in which excessive vagal tone causes sinus or nodal bradycardia.
- Due to its antimuscarinic properties, Atropine is used in the management of overdose or poisoning due to anticholinesterase compounds including organophosphorus (OP) pesticides and chemical warfare organophosphate nerve gases, muscarinic drugs as well as some muscarinic mushrooms.
- Due to its relaxing activities on smooth muscles, Atropine can be administered to treat painful manifestations related to functional disorders of the gastrointestinal tract and biliary tract.
- This relaxing activity on smooth muscles also allows the use of Atropine for spasmodic and painful manifestations of urinary tract.

VI.2.3 Unknowns relating to treatment benefits (1 short paragraph per indication of 50 words maximum)

None

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Allergy (anaphylaxis)	Atropine may induce allergic reactions.	Atropine must not be administered in case of allergy to atropine or any of the other ingredients of this medicine
Elevated pressure in the eye (increase in intraocular pressure)	Atropine may provoke a raise in pressure in the eye.	Atropine must not be administered in case of elevated pressure in the eye (glaucoma)
Urinary difficulties (urinary retention)	Atropine may induce difficulty in passing urine.	Atropine must not be administered in case of urinary difficulties
Administration in patient with myasthenia gravis (administration in patient with myasthenia gravis)	Atropine may cause aggravations of symptoms of myasthenia gravis.	Atropine must not be administered in case of myasthenia gravis unless given in conjunction with anticholinesterase
Oesophagus and intestinal disease (administration in patient with achalasia of oesophagus, paralytic ileus and obstructive disease of the gastrointestinal tract)	Atropine may induce difficulty in swallowing (dysphagia) in patients with oesophagus disease and exagerate intestinal diseases (paralytic ileus and obstructive disease)	Atropine must not be administered in case of oesophagus or intestinal disease (achalasia of oesophagus, paralytic ileus and obstructive disease of the gastrointestinal tract)
Abnormal heartbeats (arrhythmia)	Atropine may induce abnormal heartbeats	Atropine should be used with caution in case of cardiac diseases

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Medication error / risk of medication error	Despite actions implemented in terms of labelling, a residual risk of medication error remains, corresponding to the risk commonly observed for small injectable medicinal products.

Missing information

Risk	What is known
Use during pregnancy	Animal studies did not indicate direct or indirect harmful effects with respect to reproductive toxicity.

Risk	What is known
	There are limited amount of data from the use of atropine in pregnant women. Studies of the pharmacokinetics of atropine in mother and foetus in late pregnancy indicated that atropine rapidly crosses the placental barrier. Intravenous administration of atropine during pregnancy or at term may cause tachycardia in the foetus. As a precautionary measure, it is preferable to avoid the use of Atropin Stragen during pregnancy.
Long term use / iterative use	No information available
Use in patients with renal or hepatic impairment	Atropine is incompletely metabolised in the liver and is excreted in the urine as unchanged drug and metabolites.

VI.2.5 Summary of risk minimisation measures by safety concern

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.