LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Atropin Stragen
(atropine sulphate)

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(atropine sulphate)

Solution for injection pre-filled syringe, 0,2mg/ml

This is a summary of the public assessment report (PAR) for Atropin Stragen. It explains how Atropin Stragen was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Atropin Stragen.

For practical information about using Atropin Stragen, patients should read the package leaflet or contact their doctor or pharmacist.

What is Atropin Stragen and what is it used for?
Atropin Stragen is a medicine with 'well-established use'. This means that the medicinal use of the active substance of Atropin Stragen is well established in the European Union for at least ten years, with recognised efficacy and an acceptable level of safety.

Atropin Stragen is used:
- to treat a slow heart beat and conditions associated with slow heartbeat.
- before a general anaesthesia to dry up saliva and fluid in the lungs.
- as an antidote following overdose of medicines known as anticholinesterases and poisoning from some insecticides, nerve gases and mushroom poisoning.

How does Atropin Stragen work?
Atropin Stragen is one of a group of medicines called anticholinergics. Atropine sulphate, the active substance contained in Atropin Stragen, temporarily blocks some nerve endings. This decreases glands secreting, makes some muscles (such as in the gut) relax and speeds up the heart.

How is Atropin Stragen used?
The pharmaceutical form of Atropin Stragen is solution for injection pre-filled syringe for intravenous use or if necessary an intramuscular administration.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Atropin Stragen have been shown in studies?
As atropine sulphate is a well-known substance, and its use in the treatment of,

- Vagus-induced bradycardia and bradycardiac conditions in which inhibition of vagus-tone is indicated (e.g. sinus bradycardia, atrioventricular block).

- Pre-anaesthetic medication.

- Treatment of an overdose of anticholinesterases as an antidote; in the treatment of poisoning from organophosphorous insecticides or from chemical warfare 'nerve' gases and in the treatment of mushroom poisoning.

is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of atropine sulphate for above treatment.

What are the possible side effects of Atropin Stragen?
For the full list of all side effects reported with Atropin Stragen, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Atropin Stragen approved?
The use of Atropin Stragen in the treatment of,

- Vagus-induced bradycardia and bradycardiac conditions in which inhibition of vagus-tone is indicated (e.g. sinus bradycardia, atrioventricular block).

- Pre-anaesthetic medication.

- Treatment of an overdose of anticholinesterases as an antidote; in the treatment of poisoning from organophosphorous insecticides or from chemical warfare 'nerve' gases and in the treatment of mushroom poisoning.

is well-established in medical practice and documented in the scientific literature. No new or unexpected safety concerns arose from these applications. Therefore, the Medical Products Agency in Sweden decided that Atropin Stragen's benefits are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Atropin Stragen?
A risk management plan has been developed to ensure that Atropin Stragen is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Atropin Stragen, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Atropin Stragen
The marketing authorisation for Atropin Stragen was granted on 2016-06-16 in Sweden.

The full PAR for Atropin Stragen can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Atropin Stragen, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2016-07.