

Summary Public Assessment Report

Atropin Abboxia (atropine sulfate)

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Atropin Abboxia
atropine sulfate (monohydrate), atropine

Solution for injection, 0,5 mg/ml, 1 mg/ml

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

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Atropin Abboxia and what is it used for?

The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Atropin Mylan.

The product is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance, but is available in a different strength.

The reference medicine for the product is Atropin Mylan.

The product is used in the treatment of:

- relaxation of muscles in the gastro-intestinal tract during cramps
- to reduce saliva, fluid in the lungs and/or gastric juice
- to treat a slow heartbeat
- as medication during surgery.

How does Atropin Abboxia work?

Atropin Abboxia belongs to a group of medicines which are called anticholinergics. Atropine sulphate, the active substance in Atropin Abboxia, 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 Abboxia used?

The pharmaceutical form is solution for injection.

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 in Sweden.

What benefits of Atropin Abboxia have been shown in studies?

No additional studies were needed as the product is a generic medicine that is given by intravenous injection and contains the same active substance as the reference medicine, Atropin Mylan.

What are the possible side effects from Atropin Abboxia?

Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of side effects, see section 4 of the package leaflet.

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

Why is Atropin Abboxia approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be therapeutically equivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Atropin Mylan, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Atropin Abboxia?

A risk management plan has been developed to ensure that the product 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, 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 Abboxia

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

This summary was last updated in 2024-01.