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Sugammadex Adroiq (*sugammadex*)

An overview of Sugammadex Adroiq and why it is authorised in the EU

What is Sugammadex Adroiq and what is it used for?

Sugammadex Adroiq is a medicine used to reverse the effect of the muscle relaxants rocuronium and vecuronium. Muscle relaxants are medicines used during some types of operation to make the muscles relax, including the muscles that help the patient to breathe. Muscle relaxants make it easier for the surgeon to do the operation. Sugammadex Adroiq is used to speed up the recovery from the muscle relaxant, usually at the end of the operation.

Sugammadex Adroiq can be used in adults who have received rocuronium and vecuronium, and in children aged 2 years or older who have received rocuronium.

Sugammadex Adroiq is a 'generic medicine'. This means that Sugammadex Adroiq contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU. The reference medicine for Sugammadex Adroiq is Bridion. For more information on generic medicines, see the question-and-answer document here.

Sugammadex Adroiq contains the active substance sugammadex.

How is Sugammadex Adroiq used?

Sugammadex Adroiq can only be obtained with a prescription. It is given by or under the supervision of an anaesthetist (a doctor specialised in anaesthesia). Sugammadex Adroiq is given into a vein as a single bolus injection (given all at once).

For more information about using Sugammadex Adroiq, see the package leaflet or contact your doctor or pharmacist.

How does Sugammadex Adroiq work?

The active substance in Sugammadex Adroiq, sugammadex attaches to the muscle relaxants rocuronium and vecuronium, stopping them from having an effect. As a result, the muscles contract and begin to work normally again, including the muscles that help the patient to breathe.

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How has Sugammadex Adroiq been studied?

Studies on the benefits and risks of the active substance in the authorised uses have already been carried out with the reference medicine, Bridion, and do not need to be repeated for Sugammadex Adroiq.

As for every medicine, the company provided studies on the quality of Sugammadex Adroiq. There was no need for 'bioequivalence' studies to investigate whether Sugammadex Adroiq is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because Sugammadex Adroiq is given by injection into a vein, so the active substance is delivered straight into the bloodstream.

What are the benefits and risks of Sugammadex Adroiq?

Because Sugammadex Adroiq is a generic medicine, its benefits and risks are taken as being the same as the reference medicine's.

For the list of side effects and restrictions with Sugammadex Adroiq, see the package leaflet.

Why is Sugammadex Adroiq authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Sugammadex Adroiq has been shown to be comparable to Bridion. Therefore, the Agency's view was that, as for Bridion, the benefits of Sugammadex Adroiq outweigh the identified risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Sugammadex Adroiq?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Sugammadex Adroiq have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Sugammadex Adroiq are continuously monitored. Suspected side effects reported with Sugammadex Adroiq are carefully evaluated and any necessary action taken to protect patients.

Other information about Sugammadex Adroiq

Sugammadex Adroiq received a marketing authorisation valid throughout the EU on 26 May 2023.

Further information on Sugammadex Adroiq can be found on the Agency's website: www.ema.europa.eu/medicines/human/EPAR/sugammadex-adroiq. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 05-2023.