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Sugammadex Piramal (*sugammadex*)

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

What is Sugammadex Piramal and what is it used for?

Sugammadex Piramal 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 Piramal is used to speed up the recovery from the muscle relaxant, usually at the end of the operation.

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

Sugammadex Piramal is a 'generic medicine'. This means that Sugammadex Piramal 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 Piramal is Bridion. For more information on generic medicines, see the question-and-answer document here.

Sugammadex Piramal contains the active substance sugammadex.

How is Sugammadex Piramal used?

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

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

How does Sugammadex Piramal work?

The active substance in Sugammadex Piramal, 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 Piramal 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 Piramal.

As for every medicine, the company provided studies on the quality of Sugammadex Piramal. There was no need for 'bioequivalence' studies to investigate whether Sugammadex Piramal is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because Sugammadex Piramal 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 Piramal?

Because Sugammadex Piramal 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 Piramal, see the package leaflet.

Why is Sugammadex Piramal authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Sugammadex Piramal has been shown to be comparable to Bridion. Therefore, the Agency's view was that, as for Bridion, the benefits of Sugammadex Piramal 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 Piramal?

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

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

Other information about Sugammadex Piramal

Sugammadex Piramal received a marketing authorisation valid throughout the EU on 23 June 2023.

Further information on Sugammadex Piramal can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/sugammadex-piramal

This overview was last updated in July 2023.