EMA/612933/2022
EMEA/H/C/005760

Sugammadex Fresenius Kabi (*sugammadex*)

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

What is Sugammadex Fresenius Kabi and what is it used for?

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

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

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

How is Sugammadex Fresenius Kabi used?

Sugammadex Fresenius Kabi can only be obtained with a prescription. It is given by or under the supervision of an anaesthetist (a doctor specialised in anaesthesia). Sugammadex Fresenius Kabi is given into a vein as a single 'bolus' injection (given all at once). The dose depends on the patient's body weight and on how much the muscle relaxant is affecting the muscles.

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

How does Sugammadex Fresenius Kabi work?

The active substance in Sugammadex Fresenius Kabi, sugammadex, is a 'selective relaxant binding agent'. This means that it attaches to the muscle relaxants rocuronium and vecuronium forming a 'complex' that inactivates the muscle relaxants and stops them having an effect. As a result, the muscles contract and begin to work normally again, including the muscles that help the patient to breathe.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

How has Sugammadex Fresenius Kabi been studied?

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

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

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

Why is Sugammadex Fresenius Kabi authorised in the EU?

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

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

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

Other information about Sugammadex Fresenius Kabi

Sugammadex Fresenius Kabi received a marketing authorisation valid throughout the EU on 15 July 2022.

Further information on Sugammadex Fresenius Kabi can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/sugammadex-fresenius-kabi. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 07-2022.