EMADOC-1829012207-24008
Human Medicines Division
EMEA/H/C/005403

# Sugammadex Mylan (*sugammadex*)

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

## What is Sugammadex Mylan and what is it used for?

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

Sugammadex Mylan can be used in adults who have received rocuronium and vecuronium, and in children from birth who have received rocuronium.

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

## How is Sugammadex Mylan used?

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

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

## How does Sugammadex Mylan work?

The active substance in Sugammadex Mylan, sugammadex, attaches to the muscle relaxants rocuronium and vecuronium forming , 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 Mylan 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 Mylan.

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

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

## Why is Sugammadex Mylan authorised in the EU?

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

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

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

## Other information about Sugammadex Mylan

Sugammadex Mylan received a marketing authorisation valid throughout the EU on 15 November 2021.

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

This overview was last updated in 06-2025.