

Summary Public Assessment Report

Sugammadex Bioglan (sugammadex sodium)

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Sugammadex Bioglan
sugammadex sodium, sugammadex

Solution for injection, 100 mg/ml

This is a summary of the public assessment report (PAR) for Sugammadex Bioglan. 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 Sugammadex Bioglan 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 Bridion.

This medicine contains the active substance sugammadex. Sugammadex Bioglan is considered to be a *Selective Relaxant Binding Agent* since it only works with specific muscle relaxants, rocuronium bromide or vecuronium bromide.

During some types of operations, the patient’s muscles must be completely relaxed. This makes it easier for the surgeon to do the operation. For this, the general anaesthetic given includes medicines to make the muscles relax. These are called *muscle relaxants*, and examples include rocuronium bromide and vecuronium bromide. Because these medicines also make the breathing muscles relax, the patient needs help to breathe (artificial ventilation) during and after the operation until they can breathe on their own again.

Sugammadex Bioglan is used to speed up the recovery of the patient’s muscles after an operation to allow them to breathe on their own again earlier.

Sugammadex Bioglan can be used in adults whenever rocuronium bromide or vecuronium bromide is used and in children and adolescents (aged 2 to 17 years) when rocuronium bromide is used for a moderate level of relaxation.

How does Sugammadex Bioglan work?

Sugammadex Bioglan speeds up the recovery of the patient’s muscles after an operation by combining with the rocuronium bromide or vecuronium bromide in the patient’s body.

How is Sugammadex Bioglan 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 Sugammadex Bioglan have been shown in studies?

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

What are the possible side effects from Sugammadex Bioglan?

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 Sugammadex Bioglan approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Bridion, 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 Sugammadex Bioglan?

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 Sugammadex Bioglan

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

This summary was last updated in 2023-03.