

Summary Public Assessment Report

Natriumoxibat Reig Jofre (sodium oxybate)

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(sodium oxybate)

Oral solution 500 mg/ml

This is a summary of the public assessment report (PAR) for Natriumoxibat Reig Jofre. It explains how Natriumoxibat Reig Jofre was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Natriumoxibat Reig Jofre.

For practical information about using Natriumoxibat Reig Jofre, patients should read the package leaflet or contact their doctor or pharmacist.

What is Natriumoxibat Reig Jofre and what is it used for?

Natriumoxibat Reig Jofre is a ‘generic medicine’. This means that Natriumoxibat Reig Jofre is similar to a ‘reference medicine’ already authorised in the European Union (EU) called Xyrem.

Natriumoxibat Reig Jofre is used to treat narcolepsy with cataplexy in adults. Narcolepsy is a sleep disorder that may include attacks of sleep during normal waking hours, as well as cataplexy, sleep paralysis, hallucinations and poor sleep. Cataplexy is the onset of sudden muscle weakness or paralysis without losing consciousness, in response to a sudden emotional reaction such as anger, fear, joy, laughter or surprise.

How does Natriumoxibat Reig Jofre work?

Natriumoxibat Reig Jofre contains the active substance sodium oxybate. It works by consolidating night-time sleep, though its exact mechanism of action is unknown.

How is Natriumoxibat Reig Jofre used?

The pharmaceutical form of Natriumoxibat Reig Jofre is oral solution for oral use.

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.

What benefits of Natriumoxibat Reig Jofre have been shown in studies?

No additional studies were needed as Natriumoxibat Reig Jofre is a generic medicine considered to be bioequivalent to the reference medicine, Xyrem.

What are the possible side effects of Natriumoxibat Reig Jofre?

Because Natriumoxibat Reig Jofre 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 restrictions, see the package leaflet.

Why is Natriumoxibat Reig Jofre approved?

It was concluded that, in accordance with EU requirements, Natriumoxibat Reig Jofre has been shown to have comparable quality and to be bioequivalent to the reference medicine Xyrem. Therefore, the Medical Products Agency in Sweden decided that, as for Xyrem, 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 Natriumoxibat Reig Jofre?

A risk management plan has been developed to ensure that Natriumoxibat Reig Jofre 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 for Natriumoxibat Reig Jofre, 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.

The Marketing Authorisation Holder shall ensure that all doctors who are expected to prescribe/use Natriumoxibat Reig Jofre in adults and/or paediatric patients are provided with an educational pack containing the Summary of Product Characteristics and an appropriate educational brochure.

Other information about Natriumoxibat Reig Jofre

The marketing authorisation for Natriumoxibat Reig Jofre was granted on 2019-09-12 in Sweden.

The full PAR for Natriumoxibat Reig Jofre can be found on the following website: <http://mri.medagencies.org/Human/>. For more information about treatment with Natriumoxibat Reig Jofre, please read the [package leaflet](#) or contact your doctor or pharmacist.

This summary was last updated in 2019-10.