LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Oxytocin Grindeks
(oxytocin)

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Solution for injection/infusion 8.3 microgram/ml and 16.7 microgram/ml

This is a summary of the public assessment report (PAR) for Oxytocin Grindeks. It explains how Oxytocin Grindeks 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 Oxytocin Grindeks.

For practical information about using Oxytocin Grindeks, patients should read the package leaflet or contact their doctor or pharmacist.

What is Oxytocin Grindeks and what is it used for?

Oxytocin Grindeks is a 'generic medicine'. This means that Oxytocin Grindeks is similar to a 'reference medicine' already authorised in the European Union (EU) called Syntocinon.

Oxytocin Grindeks is used:
- to start or help contractions during childbirth (labour);
- during caesarean section;
- to prevent and control bleeding after delivery of your baby;
- to help in the management of a miscarriage.

How does Oxytocin Grindeks work?

Each Oxytocin Grindeks ampoule contains oxytocin 8.3 micrograms (equivalent to 5 IU) or 16.7 micrograms (equivalent to 10 IU) in 1 ml solution. Oxytocin is a hormone that contracts the smooth muscles in the womb.

How is Oxytocin Grindeks used?

The pharmaceutical form of Oxytocin Grindeks is solution for injection/infusion.

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 Oxytocin Grindeks have been shown in studies?

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

What are the possible side effects of Oxytocin Grindeks?

Because Oxytocin Grindeks 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 Oxytocin Grindeks approved?

It was concluded that, in accordance with EU requirements, Oxytocin Grindeks has been shown to have comparable quality and to be similar to the reference medicine Syntocinon. Therefore, the Medical Products Agency in Sweden decided that, as for Syntocinon, 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 Oxytocin Grindeks?

A risk management plan has been developed to ensure that Oxytocin Grindeks 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 Oxytocin Grindeks, 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 Oxytocin Grindeks

The marketing authorisation for Oxytocin Grindeks was granted on 2010-10-01 in Sweden.

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

This summary was last updated in 2017-08.