LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Bupivacaine Noridem
(bupivacaine hydrochloride monohydrate)

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Summary Public Assessment Report

Bupivacaine Noridem
bupivacaine hydrochloride monohydrate
Solution for injection, 2,5 mg/ml, 5 mg/ml

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

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

What is Bupivacaine Noridem and what is it used for?

Bupivacaine Noridem is a 'generic medicine'. This means that Bupivacaine Noridem is similar to a 'reference medicine' already authorised in the European Union (EU) called Marcain.

Bupivacaine Noridem is used to numb (anaesthetise) parts of the body. It is used to stop pain happening or to provide pain relief. It can be used to:

- Numb parts of the body during surgery in adults and children above 12 years.
- Relieve pain during childbirth.
- Relieve pain in adults, infants and children above 1 year of age.

How does Bupivacaine Noridem work?

Bupivacaine Noridem contains the active substance bupivacaine hydrochloride. It belongs to a group of medicines called amide-type local anaesthetics.

How is Bupivacaine Noridem used?

The pharmaceutical form of Bupivacaine Noridem 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 Bupivacaine Noridem have been shown in studies?

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

What are the possible side effects of Bupivacaine Noridem?

Because Bupivacaine Noridem 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 Bupivacaine Noridem approved?

It was concluded that, in accordance with EU requirements, Bupivacaine Noridem has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine Marcain. Therefore, the Medical Products Agency in Sweden decided that, as for Marcain, 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 Bupivacaine Noridem?

A risk management plan has been developed to ensure that Bupivacaine Noridem 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 Bupivacaine Noridem, 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 Bupivacaine Noridem

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

This summary was last updated in YYYY-MM.