LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Bupivacaine Spinal Tung Grindeks (bupivacaine hydrochloride monohydrate)

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Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@lakemedelsverket.se

Summary Public Assessment Report

Bupivacaine Spinal Tung Grindeks
bupivacaine hydrochloride (monohydrate),

Solution for injection, 5 mg/ml

This is a summary of the public assessment report (PAR) for Bupivacaine Spinal Tung Grindeks. 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 Bupivacaine Spinal Tung Grindeks 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 Marcain spinal tung.

How does Bupivacaine Spinal Tung Grindeks work?

Bupivacaine Spinal Tung Grindeks contains the active substance bupivacaine hydrochloride. It is a local anaesthetic used to numb (anaesthetise) the lower parts of the body during surgery in adults and children of all ages. It is used, for example, to numb legs to be operated on, in urological surgery or in abdominal surgery.

The medicinal product temporarily blocks the nerve signals in the area where it is injected and it temporarily reduce or remove the sensation in certain part of the body.

How is Bupivacaine Spinal Tung Grindeks used?

The pharmaceutical form is solution for injection for use in 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 Spinal Tung Grindeks have been shown in studies?

No additional studies were needed as the product is a generic medicine that is given by injection and contains the same active substance as the reference medicine, Marcain spinal tung.

What are the possible side effects from Bupivacaine Spinal Tung Grindeks?

Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

Why is Bupivacaine Spinal Tung Grindeks 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 Marcain spinal tung, 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 Spinal Tung Grindeks?

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 Bupivacaine Spinal Tung Grindeks

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

This summary was last updated in YYYY-MM.