LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Bupivacaine Spinal Tung Aguettant
(bupivacaine hydrochloride (monohydrate))

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Bupivacaine Spinal Tung Aguettant
bupivacaine hydrochloride (monohydrate)

Solution for injection, 5 mg/ml

This is a summary of the public assessment report (PAR) for Bupivacaine Spinal Tung Aguettant. 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 Aguettant 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.

Bupivacaine Spinal Tung Aguettant 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 lower abdominal surgery.

How does Bupivacaine Spinal Tung Aguettant work?
The medicine temporarily blocks the nerve signals in the area where it is injected and it temporarily reduces or removes the sensation in certain parts of the body.

How is Bupivacaine Spinal Tung Aguettant used?
The pharmaceutical form is Solution for injection for parenteral 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 in Sweden.

What benefits of Bupivacaine Spinal Tung Aguettant 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 Aguettant?
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 Bupivacaine Spinal Tung Aguettant approved?
It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be therapeutically equivalent 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 Aguettant?
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 Aguettant
The full PAR for Bupivacaine Spinal Tung Aguettant can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Bupivacaine Spinal Tung Aguettant , please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2024-12.