

Summary Public Assessment Report

Bupivacaine Alternova (bupivacaine hydrochloride)

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(Bupivacaine hydrochloride)

Solution for injection; 2.5 mg/ml and 5 mg/ml

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

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

What is Bupivacaine Alternova and what is it used for?

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

Bupivacaine Alternova can be used to:

- numb parts of the body during surgery in adults and adolescents above 12 years
- relieve of acute pain in adults, infants and children above 1 year of age

It is used for example in surgical operations and as relief of pain after an operation.

How does Bupivacaine Alternova work?

Bupivacaine Alternova is a local anaesthetic. It belongs to a group of medicines called amide-type local anaesthetics. It works by blocking the transmission of pain signals through nerves in or near the spinal cord. It is used to numb or make parts of the body free from pain.

How is Bupivacaine Alternova used?

The pharmaceutical form of Bupivacaine Alternova is solution for injection for subcutaneously (under the skin), intramuscularly (into a muscle), intraarticularly (into a joint) or as an epidural injection (into your back).

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 Bupivacaine Alternova have been shown in studies?

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

What are the possible side effects of Bupivacaine Alternova?

Because Bupivacaine Alternova is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine Marcain. For the full list of restrictions, see the package leaflet.

Why is Bupivacaine Alternova approved?

It was concluded that, in accordance with EU requirements, Bupivacaine Alternova has been shown to have comparable quality and to be similar 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 Alternova?

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

The marketing authorisation for Bupivacaine Alternova was granted on 2015-10-09 in Sweden.

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

This summary was last updated in 2015-10.