

Package leaflet: Information for the user

Marcain Polyamp Steripack 0.25% w/v and 0.5% w/v Solution for Injection bupivacaine hydrochloride

Read all of this leaflet carefully before this medicine is given to you because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Marcain Polyamp Steripack is and what it is used for
2. What you need to know before Marcain Polyamp Steripack is given to you
3. How Marcain Polyamp Steripack is given to you
4. Possible side effects
5. How to store Marcain Polyamp Steripack
6. Contents of the pack and other information

1. What Marcain Polyamp Steripack is and what it is used for

Marcain Polyamp Steripack contains a medicine called bupivacaine hydrochloride. It belongs to a group of medicines called local anaesthetics.

Marcain Polyamp Steripack 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 in adults, infants and children above 1 year of age.

2. What you need to know before Marcain Polyamp Steripack is given to you

You must not be given Marcain Polyamp Steripack:

- If you are allergic to bupivacaine hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- If you are allergic to any other local anaesthetics of the same class (such as lidocaine or ropivacaine).
- If you have a skin infection near to where the injection will be given.

You must not be given this medicine if any of the above apply to you. If you are not sure, talk to your doctor or nurse before you are given this medicine.

Warnings and precautions

Talk to your doctor or nurse before having Marcain Polyamp Steripack:

- If you have heart, liver or kidney problems. This is because your doctor may need to adjust the dose of Marcain Polyamp Steripack. Problems with your liver enzymes may occur, particularly if you have long-term treatment with this medicine.
- If you have epilepsy.
- If you have been told that you have decreased volume of blood (hypovolaemia).

Children

- In children aged less than 12 years as some injections of Marcain Polyamp Steripack in order to numb parts of the body during surgery are not established in younger children. The use of Marcain Polyamp Steripack is not established in children less than 1 year of age.

If you are not sure if any of the above apply to you, talk to your doctor or nurse before you are given this medicine.

Other medicines and Marcain Polyamp Steripack

Tell your doctor if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Marcain Polyamp Steripack can affect the way some medicines work and some medicines can have an effect on Marcain Polyamp Steripack.

In particular, tell your doctor if you are taking any of the following medicines:

- Medicines used to treat an uneven heart beat (arrhythmia) such as lidocaine, mexiletine or amiodarone. Your doctor needs to know about these medicines to be able to work out the correct dose of Marcain Polyamp Steripack for you.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think that you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine

Driving and using machines

Marcain Polyamp Steripack may make you feel sleepy and affect the speed of your reactions. After you have been given Marcain Polyamp Steripack, you should not drive or use tools or machines until the next day.

Marcain Polyamp Steripack contains sodium

This medicine contains 31.47 mg sodium (main component of cooking/table salt) in each 10 ml ampoule and 62.94 mg sodium in each 20 ml ampoule.

This is equivalent to 1.57% and 3.15% of the recommended maximum daily dietary intake of sodium for an adult.

3. How Marcain Polyamp Steripack is given to you

Marcain Polyamp Steripack will be given to you by a doctor. Your doctor will know the correct way to give you this medicine.

The dose that your doctor gives you will depend on the type of pain relief that you need and the part of your body that the medicine will be injected into. It will also depend on your body size, age, and physical condition. Usually one dose will last long enough but more doses may be given if the surgery takes a long time.

Marcain Polyamp Steripack will be given to you as an injection or infusion. The part of the body where you are injected will depend on why you are being given Marcain Polyamp Steripack. Your doctor will give you Marcain Polyamp Steripack in one of the following places:

- Near to the part of the body that needs to be numbed.
- In an area away from the part of the body that needs to be numbed. This is the case if you are given an epidural injection (an injection around the spinal cord).

When Marcain Polyamp Steripack is injected into the body in one of these ways, it stops the nerves from being able to pass pain messages to the brain. It will slowly wear off when the medical procedure is over.

Use in children and adolescents

Depending on the type of required analgesia Marcain Polyamp Steripack is injected slowly either into the epidural space (part of the spine) or other parts of the body by a doctor experienced in paediatric anaesthetic techniques. Dosage depends on the age and weight of the patient and will be determined by the doctor.

If you have been given too much Marcain Polyamp Steripack

Serious side effects from getting too much Marcain Polyamp Steripack are unlikely. They need special treatment and the doctor treating you is trained to deal with these situations. The first signs of being given too much Marcain Polyamp Steripack are usually as follows:

- Feeling dizzy or light-headed.
- Numbness of the lips and around the mouth.

- Numbness of the tongue.
- Hearing problems.
- Problems with your sight (vision).

To reduce the risk of serious side effects, your doctor will stop giving you Marcain Polyamp Steripack as soon as these signs appear. This means that if any of these happen to you, or you think you have received too much Marcain Polyamp Steripack, **tell your doctor immediately**.

More serious side effects from being given too much Marcain Polyamp Steripack include twitching of your muscles, fits (seizures), being sick (vomiting) and loss of consciousness.

4. Possible side effects

Like all medicines, this medicine can cause side effects although not everybody gets them.

Severe allergic reactions (rare, may affect up to 1 in 1,000 people)

If you have a severe allergic reaction, **tell your doctor immediately**. The signs may include sudden onset of:

- Swelling of your face, lips, tongue or throat. This may make it difficult to swallow.
- Severe or sudden swelling of your hands, feet and ankles.
- Difficulty breathing.
- Severe itching of the skin (with raised lumps).

Other possible side effects:

Very common (may affect more than 1 in 10 people)

- Low blood pressure. This might make you feel dizzy or light-headed.
- Feeling sick (nausea).

Common (may affect up to 1 in 10 people)

- Being sick (vomiting).
- Feeling dizzy.
- Pins and needles.
- High blood pressure (hypertension).
- Slow heart beat.
- Problems passing water.

Uncommon (may affect up to 1 in 100 people)

- Feeling light-headed.
- Fits (seizures).
- Numbness of the tongue or around the mouth.
- Ringing in the ears or being sensitive to sound.
- Difficulty in speaking.
- Blurred sight or double vision.
- Loss of consciousness.
- Shaking (tremors).
- Twitching of your muscles.

Rare (may affect up to 1 in 1,000 people)

- Nerve damage that may cause changes in sensation or muscle weakness (neuropathy). This may include peripheral nerve damage.
- A condition called arachnoiditis (inflammation of the membrane that surrounds the spinal cord). The signs include a stinging or burning pain in the lower back or legs and tingling, numbness or weakness in the legs.
- Weak or paralysed legs.
- Uneven heart beat (arrhythmias). This could be life-threatening.

- Slowed or stopped breathing or stopped heart beat. This could be life-threatening.

Possible side effects seen with other local anaesthetics which might also be caused by Marcain Polyamp Steripack include:

- Damaged nerves. Rarely this may cause permanent problems.
- Blindness which is not permanent or problems with the muscles of the eyes that are long-lasting. This may happen with some injections given around the eyes.

Additional side effects in children and adolescents

Side effects in children are similar to those in adults.

Do not be concerned by this list of possible side effects. You may not get any of them.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

HPRA Pharmacovigilance

Website: www.hpra.ie

5. How to store Marcain Polyamp Steripack

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the container after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Your doctor or the hospital will normally store Marcain Polyamp Steripack and they are responsible for the quality of the product when it has been opened. The product is for single use only. Any unused solution will be discarded. Marcain Polyamp Steripack is a clear, colourless solution. It will not be used if it does not match this description. They are also responsible for disposing of any unused Marcain Polyamp Steripack correctly.

6. Contents of the pack and other information

What Marcain Polyamp Steripack contains

The active ingredient is bupivacaine hydrochloride. Marcain Polyamp Steripack comes in two strengths. Each ml of the 0.25% w/v strength contains bupivacaine hydrochloride 2.64 mg equivalent to bupivacaine hydrochloride anhydrous 2.5 mg (25 mg per 10 ml Polyamp). Each ml of the 0.5% w/v strength contains bupivacaine hydrochloride 5.28 mg equivalent to bupivacaine hydrochloride anhydrous 5 mg (50 mg per 10 ml Polyamp).

The other ingredients are sodium chloride, sodium hydroxide/hydrochloric acid, and water for injections.

What Marcain Polyamp Steripack looks like and contents of the pack

Marcain Polyamp Steripack is a solution for injection. It comes in 10 ml or 20 ml plastic ampoules. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisations for Marcain Polyamp Steripack 0.25% w/v and 0.5% w/v are held by Aspen Pharma Trading Limited, 3016 Lake Drive, Citywest Business Campus, Dublin 24, Ireland.

Tel: +353 (0)1 6308400

Marcain Polyamp Steripack 0.25% w/v and 0.5% w/v is manufactured by AstraZeneca AB, Forskargatan 18, 151 36 Södertälje, Sweden

(Marcain Polyamp Steripack 0.5% w/v only):

Aspen Notre Dame de Bondeville, 1 Rue de l'Abbaye, 76960 Notre-Dame-de-Bondeville, France.

This leaflet was last revised in May 2024.

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