

## Package leaflet: Information for the user

### Marcain® Polyamp Steripack 0.25% and 0.5% 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.
- If you have something called cardiogenic shock (a condition where the heart is unable to supply enough blood to the body).
- If you have something called hypovolaemic shock (very low blood pressure leading to collapse).
- If you have problems with clotting of your blood.
- If you have diseases of the brain or spine such as meningitis, polio or spondylitis.
- If you have a severe headache caused by bleeding inside the head (intracranial haemorrhage).
- If you have problems with your spinal cord due to anaemia.
- If you have blood poisoning (septicaemia).
- If you have had a recent trauma, tuberculosis or tumours of the spine.

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

### **Warnings and precautions**

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

- If you have heart, kidney or liver problems. This is because your doctor may need to adjust the dose of Marcain Polyamp Steripack.
- If you have a swollen stomach due to more fluid than normal.
- If you have a stomach tumour.
- If you have been told that you have decreased volume of blood (hypovolaemia).
- If you have fluid in your lungs.

### **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 Marcain Polyamp Steripack.

### **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.
- Medicines used to stop blood clots (anti-coagulants).

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**

Marcain Polyamp Steripack contains up to 3.15 milligrams (mg) of sodium in each millilitre (ml), equivalent to 31.4 mg per 10 ml ampoule. Your doctor will take this into account if you are on a sodium controlled diet.

## **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. 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.

#### **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), and loss of consciousness.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

## **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 speaking.
- Blurred sight (vision).
- Loss of consciousness.
- Shaking (tremors).
- Twitching of your muscles.

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

- Double vision.
- 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:**

- Problems with your liver enzymes. This may happen if you have long-term treatment with this medicine.

- 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.

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 via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

## **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.
- Store below 30°C. Do not freeze.
- 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 if it is not used immediately. 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: 2.5 mg or 5 mg of bupivacaine hydrochloride per ml of solution.

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 in cartons of 5 or 10. Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

The Marketing Authorisations for Marcain Polyamp Steripack 0.25% and 0.5% are held by

Aspen Pharma Trading Limited, 3016 Lake Drive, Citywest Business Campus, Dublin 24, Ireland  
Tel: +44 (0)1 748 828 391

Marcaïn Polyamp Steripack 0.25% and 0.5% is manufactured by AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, SK10 2NA, UK and AstraZeneca AB, S-151 85 Södertälje, Sweden.

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:

<b>Product name</b>	<b>Reference number</b>
Marcaïn Polyamp Steripack 0.25%	39699/0078
Marcaïn Polyamp Steripack 0.5%	39699/0079

This is a service provided by the Royal National Institute of Blind People.

This leaflet was last revised in November 2016.

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