

## **Package leaflet: Information for the user**

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

## **1. What Marcain Heavy is and what it is used for**

The name of your medicine is 'Marcain Heavy Steripack 0.5% w/v Solution for Injection'. It is referred to as Marcain Heavy in the rest of this leaflet. Marcain Heavy contains the active substance called bupivacaine hydrochloride. It belongs to a group of medicines called local anaesthetics.

Marcain Heavy is used to numb (anaesthetise) parts of the body during surgery in adults and children of all ages. It stops pain happening during surgery (operations).

## **2. What you need to know before Marcain Heavy is given to you**

#### **You must not be given Marcain Heavy:**

- 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 at or near to where the injection will be given.
- If you have blood poisoning (septicaemia).
- If you have something called cardiogenic shock (a serious 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 are having a medicine to prevent or treat blood clots (anti-coagulants).
- 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 increased pressure in your brain.
- If you have problems with your spinal cord due to anaemia.
- If you have had a recent trauma, tuberculosis or tumours of the spine.

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

#### **Warnings and precautions**

Talk to your doctor or nurse before having Marcain Heavy:

- If you have heart, liver or kidney problems. This is because your doctor may need to adjust the dose of Marcain Heavy.

- If you have been told that you have decreased volumes of blood (hypovolaemia).
- If you have a large build up of fluid around your abdomen (ascites).
- If you have a large tumour in your abdomen.
- If you have fluid in your lungs.
- If you have a nerve problem, such as multiple sclerosis or being paralysed.
- If you have a problem affecting your nerves and muscles (neuromuscular disorder).
- If you are elderly.

If you are not sure if any of the above apply to you, talk to your doctor or nurse before using Marcain Heavy.

### **Other medicines and Marcain Heavy**

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 Heavy can affect the way some medicines work and some medicines can have an effect on Marcain Heavy.

You must not be given Marcain Heavy if you are having the following:

- A medicine to prevent or treat blood clots (anti-coagulants).

Also tell your doctor if you are taking any of the following medicines:

- Other local anaesthetics.
- Medicines used to treat an uneven heart beat (arrhythmia), such as amiodarone.

Your doctor needs to know about these medicines to be able to work out the correct dose of Marcain Heavy 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 Heavy may make you feel sleepy and affect the speed of your reactions. After you have been given Marcain Heavy, you should not drive or use tools or machines until the next day.

### **Marcain Heavy contains sodium**

This medicinal product contains less than 1 mmol sodium (23 mg) per ampoule, that is to say essentially 'sodium-free'.

## **3. How Marcain Heavy is given to you**

### **Use in adults**

Marcain Heavy will be given to you by a doctor, who will decide the correct dose. It will be given to you as an injection into the lower part of your spine.

### **Use in children and adolescents**

Marcain Heavy is injected slowly into the spinal channel (part of the spine) 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.

When Marcain Heavy is injected, it stops the nerves from being able to pass pain messages to the brain.

### **If you have been given too much Marcain Heavy**

Serious side effects from getting too much Marcain Heavy need special treatment and the doctor treating you is trained to deal with these situations. The first signs of being given too much Marcain Heavy 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 Heavy 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 Heavy, **tell your doctor immediately**.

More serious side effects from being given too much Marcain Heavy include tremors, fits (seizures) and heart problems.

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).
- Very low blood pressure which can make you feel faint or collapse.

### **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).
- Slow heart beat.

#### **Common (may affect up to 1 in 10 people)**

- Headache.
- Being sick (vomiting).
- Difficulty in passing urine or being incontinent.

#### **Uncommon (may affect up to 1 in 100 people)**

- Itching, numbness, burning or tingling of the skin.
- Back pain.
- Muscle weakness for a short time.

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

- Sudden stopping of the heart beat (cardiac arrest).
- Difficulty breathing.
- Weakness or loss of feeling or loss of movement in your lower body.
- Long-lasting pain in your back or legs.
- Reduced or strange sensation or feeling in the skin.

Some symptoms can happen if the injection was given in the wrong way by mistake, or if you have been given it with other local anaesthetics. These include fits (seizures), feeling dizzy or light-headed, trembling and numbness of the tongue.

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

- Damaged nerves. Rarely (affecting less than 1 in 1,000 people), this may cause permanent problems.
- If too much Marcain Heavy is given into the spinal fluid, the whole body may become numbed (anaesthetised).

#### **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.

#### **Ireland**

HPRA Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie)

#### **Malta**

ADR Reporting Website: [www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal)

## **5. How to store Marcain Heavy**

- 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. Store the ampoules in the original carton in order to protect from light.
- Your doctor or the hospital will normally store Marcain Heavy. When an ampoule is opened the solution should be used immediately. Your doctor or the hospital are also responsible for disposing of any unused Marcain Heavy correctly.

## **6. Contents of the pack and other information**

#### **What Marcain Heavy contains**

The active ingredient is bupivacaine hydrochloride anhydrous. Each millilitre (ml) of solution contains 5 mg of bupivacaine hydrochloride anhydrous.

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

#### **What Marcain Heavy looks like and contents of the pack**

Marcain Heavy is a clear, colourless solution for injection. It comes in 5 ml type I (Ph. Eur) clear glass ampoules. Each ampoule contains 4 ml of solution for injection. The product comes in blisters of 5 ampoules.

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

The Marketing Authorisation for Marcain Heavy marketed in Ireland and Malta is held by Aspen Pharma Trading Limited, 3016 Lake Drive, Citywest Business Campus, Dublin 24, Ireland

IE Tel: +353 (0)1 6308400

MT Tel: +356 21497982

Marcain Heavy is manufactured by Cenexi, 52 Rue Marcel et Jacques Gaucher, 94120 Fontenay sous Bois, France.

**This leaflet was last revised in June 2022.**

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