

Company: PANPHARMA	
Product: Bupivacaine Heavy 5 mg/ml, solution for injection	
Module: 1. Administrative information and prescribing information	
Section: 1.3.1.: SPC, Labelling and package leaflet	

## **B. PACKAGE LEAFLET**

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

#### **Bupivacaine Heavy 5 mg/ml, solution for injection** bupivacaine hydrochloride

**Read all of this leaflet carefully before you are given this medicine 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 Bupivacaine Heavy is and what it is used for
2. What you need to know before you are given Bupivacaine Heavy
3. How Bupivacaine Heavy is given
4. Possible side effects
5. How to store Bupivacaine Heavy
6. Contents of the pack and other information

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

Bupivacaine Heavy contains the active substance called bupivacaine hydrochloride. It belongs to a group of medicines called local anaesthetics.

Bupivacaine 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: urological or lower limbs surgery, including hip surgery, and lower abdominal surgery (including caesarean section).

#### **2. What you need to know before you are given Bupivacaine Heavy**

##### **Bupivacaine Heavy must not be given:**

- 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 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 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 had a recent trauma, tuberculosis or tumours of the spine.

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.

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### **Warnings and precautions**

Talk to your doctor or nurse before Bupivacaine Heavy is given to you:

- If you are elderly and are in a generally weak condition
- If you have heart, liver or kidney problems. This is because your doctor may need to adjust the dose of this medicine.
- If you have been told that you have decreased volumes of blood (hypovolaemia).
- If you have fluid in your lungs.

Bupivacaine should not be injected into inflamed or infected areas.

Additionally, your doctor will take special care if you are suffering from some disorders affecting nerves such as multiple sclerosis (tissue turnover in brain and spinal cord), hemiplegia (one-sided paralysis), paraplegia (double-sided paralysis) or other muscle-nerve disease .

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 Bupivacaine Heavy**

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines. Taking some medicines together can be harmful. Remember that the doctor at hospital may not have been informed if you have recently begun a course of treatment for another illness.

In particular, inform your doctor if you are taking:

- Other local anaesthetics (such as lidocaine)
- Medicines to control your heart beat (including mexiletine, tocainide)
- Cimetidine (a medicine used to treat heartburn, stomach or intestinal ulcers)
- Verapamil (a medicine used for heart problems, migraines, etc.)
- ACE inhibitors (medicines used to control blood pressure or in heart diseases; such as enalapril, ramipril, etc.)

Using bupivacaine and propofol (a medicine used for general anaesthesia) at the same time may increase the hypnotic effect of the propofol.

Additionally, you must also inform your doctor or nurse in the case that you have taken any other medicines related to heart disease.

### **Pregnancy and breast-feeding**

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

Bupivacaine Heavy can be used during pregnancy and breast-feeding. The dose will be adjusted by your doctor if you are in the late stage of pregnancy.

### **Driving and using machines**

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

### **Bupivacaine Heavy contains sodium**

This medicine contains less than 1 mmol of sodium (23 mg) per ampoule, that is to say essentially “sodium-free”.

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### 3. How Bupivacaine Heavy is given

Bupivacaine 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.

Dosage depends on the age and weight of the patient and will be determined by the doctor.

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

#### Use in children and adolescents

Bupivacaine Heavy is injected slowly into the spinal channel (part of the spine) by a doctor experienced in paediatric anaesthetic techniques.

#### If you use more Bupivacaine Heavy than you should

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

- Low blood pressure,
- Slow pulse,
- Irregular heartbeat,
- 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 Bupivacaine 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 Bupivacaine Heavy, **tell your doctor immediately**.

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

### 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:

- 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 in 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).

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- Slow heartbeat.

**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)

- Heart attack.
- Difficulty in 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 this medicine 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 Bupivacaine Heavy include:

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

**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 national reporting system Yellow Card Scheme Website:

United Kingdom:

[www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland:

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

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

E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Bupivacaine Heavy

Keep this medicine out of the sight and reach of children.

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Do not use this medicine after the expiry date which is stated on the ampoule after EXP. The expiry date refers to the last day of that month.

Bupivacaine Heavy is for single use only and should be used immediately after opening. Discard any unused solution.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

### What Bupivacaine Heavy contains

- The active substance is bupivacaine hydrochloride. Each millilitre (ml) of solution contains 5 mg of bupivacaine hydrochloride (as bupivacaine hydrochloride anhydrous).
- The other ingredients are: glucose monohydrate, sodium hydroxide and hydrochloric acid (for pH adjustment), water for injection.

### What Bupivacaine Heavy looks like and contents of the pack

Bupivacaine Heavy is a clear, colourless solution for injection. It comes in glass ampoules containing 4 ml of solution (equivalent to 20 mg of bupivacaine hydrochloride).

Box of 1, 5 and 10 ampoules. Not all pack sizes may be marketed.

## Marketing Authorisation Holder and Manufacturer

### Marketing Authorisation Holder

**PANPHARMA**

Z.I. du Clairay

35133 Luitré

FRANCE

### Manufacturer

**PANPHARMA GmbH**

Bunsenstrasse 4

22946 Trittau

GERMANY

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Denmark	Pankaine Spinal tung
Finland	Pankaine Spinal tung 5 mg/ml, injektioneste, liuos
Norway	Pankaine Spinal tung
Ireland	Bupivacaine Heavy 5 mg/ml, solution for injection
United Kingdom	Bupivacaine Heavy 5 mg/ml, solution for injection
Sweden	Pankaine Spinal tung
Netherlands	Pankaine Glucose 5 mg/ml, oplossing voor injectie

**This leaflet was last revised in October 2019**

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The following information is intended for healthcare professionals only:

This medicinal product is for intrathecal use only (see section 3).

As with all parenteral drugs, the solution should be inspected prior to use. Only clear solutions without visible particles may be used.

For single use only.

The solution should be used immediately after the ampoule is opened.

Any remaining solution should be discarded.

Medicines should not be disposed of via wastewater or household waste.