

PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

MACAINE HCl 0,5 % SPINAL INJECTION WITH DEXTROSE

spinal injection

Bupivacaine hydrochloride 20 mg (5 mg/mL)

Contains sugar: Dextrose anhydrous 290,8 mg (72,7 mg/mL)

(equivalent to dextrose monohydrate 320 mg (80 mg/mL))

Read all of this leaflet carefully before you are administered MACAINE HCl

0,5 % SPINAL INJECTION WITH DEXTROSE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet

1. What MACAINE HCl 0,5 % SPINAL INJECTION WITH DEXTROSE is and what it is used for

2. What you need to know before you are given MACAINE HCl 0,5 % SPINAL INJECTION WITH DEXTROSE

3. How MACAINE HCl 0,5 % SPINAL INJECTION WITH DEXTROSE is given to you

4. Possible side effects

5. How to store MACAINE HCl 0,5 % SPINAL INJECTION WITH DEXTROSE
6. Contents of the pack and other information

1. What MACAINE HCl 0,5 % SPINAL INJECTION WITH DEXTROSE is and what it is used for

MACAINE HCl 0,5 % SPINAL INJECTION WITH DEXTROSE contains the active ingredient bupivacaine, which belongs to a group of medicines called amide type local anaesthetics, that is injected into the surrounding areas of the spinal cord.

It is used to numb (anaesthetise) parts of the body during surgical operations which prevents pain and discomfort.

2. What you need to know before you are given MACAINE HCl 0,5 % SPINAL INJECTION WITH DEXTROSE

MACAINE HCl 0,5 % SPINAL INJECTION WITH DEXTROSE should not be administered to you:

- If you are hypersensitive (allergic) to bupivacaine hydrochloride or any other local anaesthetic of the same class, or any of the other ingredients of MACAINE HCl 0,5 % SPINAL INJECTION WITH DEXTROSE (listed in section 6)
- If you are pregnant (except for use during labour)
- 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 (a condition in which there is a deficiency of red cells or of haemoglobin in the blood)
- If you have had a recent trauma, tuberculosis or tumours of the spine
- If you have blood poisoning (septicaemia)
- If you have a skin infection near to where the injection will be given
- 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.

Warnings and precautions

Tell your doctor or health care provider before being given MACAINE HCl 0,5 %

SPINAL INJECTION WITH DEXTROSE if:

- You suffer from any heart problems
- You are over the age of 65
- You are in the late stages of pregnancy
- You have been told that you have a decreased volume of blood (hypovolaemia)
- You have fluid in your lungs
- You suffer from any liver problems, as this may cause an accumulation of bupivacaine in the blood, leading to toxic effects.

Other medicines and MACAINE HCl 0,5 % SPINAL INJECTION WITH DEXTROSE

Always tell your health care provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

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

- Other local anaesthetics
- Medicines used to treat an uneven heartbeat (dysrhythmia), such as lidocaine (lignocaine) or amiodarone.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before been given this medicine.

Safe use of MACAINE HCl 0,5 % SPINAL INJECTION WITH DEXTROSE in pregnant women, other than in labour, has not yet been established and therefore should not be given in early pregnancy.

Bupivacaine is excreted into breast milk.

Driving and using machines

MACAINE HCl 0,5 % SPINAL INJECTION WITH DEXTROSE may make you feel sleepy and influence your reactions when driving or using tools or machines. You should wait for the effect to wear off before resuming these activities.

3. How MACAINE HCL 0,5 % SPINAL INJECTION WITH DEXTROSE is given to you

You will not be expected to give yourself MACAINE HCl 0,5 % SPINAL INJECTION WITH DEXTROSE. It will be given to you by a person who is qualified to do so.

The recommended 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 for the surgical procedure that you will have.

If you are given more MACAINE HCl 0,5 % SPINAL INJECTION WITH DEXTROSE than you should

Since a health care provider will administer this medicine, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

The first signs of being given too much MACAINE HCl 0,5 % SPINAL INJECTION WITH DEXTROSE are:

- Feeling sick (nauseous)
- Hearing problems
- Numbness of the tongue
- Feeling dizzy or light-headed
- Having problems with your sight (blurred vision)
- Tremors followed by feeling sleepy.

To reduce the risk of serious side effects, your doctor will stop giving you this injection as soon as these signs appear. This means that if any of these happen to you, or you think you have received too much MACAINE HCl 0,5 % SPINAL INJECTION WITH DEXTROSE, tell your doctor immediately. More serious side effects from being given too much MACAINE HCl 0,5 % SPINAL INJECTION WITH DEXTROSE include twitching of your muscles, fits (seizures), and loss of consciousness.

4. Possible side effects

MACAINE HCl 0,5 % SPINAL INJECTION WITH DEXTROSE can have side effects.

Not all side effects reported for MACAINE HCl 0,5 % SPINAL INJECTION WITH DEXTROSE are included in this leaflet. Should your general health worsen or if you experience any untoward effects when given this medicine, please consult your healthcare provider for advice.

If any of the following happen, tell your doctor immediately:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- Rash or itching
- Very low blood pressure which can make you feel faint or collapse.

These are all very serious side effects. If you have them, you may have had a serious reaction to MACAINE HCl 0,5 % SPINAL INJECTION WITH DEXTROSE. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you notice any of the following:

- Tremors (involuntary, rhythmic contractions of your muscles)
- Severe drowsiness (leading to unconsciousness)
- Difficulty breathing.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache
- Low blood pressure. This might make you feel dizzy or light-headed
- Feeling sick (nausea) or being sick (vomiting)
- Slow heart beat
- Inability to control urination or bowel movements.

Less frequent side effects:

- Itching, numbness, burning or tingling of the skin
- Back pain
- Muscle weakness for a short time
- Weakness or loss of feeling or loss of movement in your lower body
- Long-lasting pain in your back or legs
- Heart attack
- Difficulty breathing
- Slowing of breathing.

If you notice any side effects not mentioned in this leaflet, please inform your healthcare provider.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc-org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of MACAINE HCl 0,5 % SPINAL INJECTION WITH DEXTROSE.

For reporting of side effects directly to the Holder of the Certificate of Registration, contact +27 11 635 0134 or email Adcock.aereports@adcock.com

5. How to store MACAINE HCl 0,5 % SPINAL INJECTION WITH DEXTROSE

Store at or below 25 °C

The solution must not be stored in such a way that it can be influenced by metals, e.g. needles or metal parts of syringes, as dissolved metal ions may cause swelling at the site of the injection.

The solution should be used immediately after opening of the ampoule. Any remaining solution should be discarded.

Keep in original container until required for use.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What MACAINE HCl 0,5 % SPINAL INJECTION WITH DEXTROSE contains

The active substance is bupivacaine hydrochloride.

The other ingredients are dextrose anhydrous (as monohydrate), sodium hydroxide (for pH adjustment) and water for injections.

**What MACAINE HCl 0,5 % SPINAL INJECTION WITH DEXTROSE looks like
and contents of the pack**

A clear colourless solution of 4 mL packed in a 5 mL Type I clear one-point cut (OPC) glass closed ampoule in packs of 10.

The ampoules are placed in an outer cardboard carton.

Holder of Certificate of Registration

Adcock Ingram Critical Care (Pty) Ltd

1 Sabax Road

Aeroton

Johannesburg

2013

Tel: +27 11 494 8000

This leaflet was last revised in

27 October 2025

Registration number

U/4/91

Namibia: NS2 90/4/00135

Email: AICC.RegulatoryAffairs@adcock.com



MACAINE HCl 0,5 % SPINAL INJECTION WITH DEXTROSE
Spinal Injection

Adcock Ingram Critical Care (Pty) Ltd.
27 October 2025

Botswana: S2 B9300535