

PATIENT INFORMATION LEAFLET

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SCHEDULING STATUS: S4

MACAINE HCl 0,5 % INJECTION

Bupivacaine hydrochloride

Sugar free

**Read all of this leaflet carefully before you are administered MACAINE HCl
0,5 % INJECTION**

- 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 % INJECTION is and what it is used for
2. What you need to know before you are given MACAINE HCl 0,5 %
INJECTION
3. How to receive MACAINE HCl 0,5 % INJECTION
4. Possible side effects
5. How to store MACAINE HCl 0,5 % INJECTION
6. Contents of the pack and other information

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

MACAINE HCl 0,5 % is a local anaesthetic and belongs to a group of medicines called amide-type anaesthetics. It produces loss of feeling or sensation that is confined to one part of the body. MACAINE HCl 0,5 % is used for surgical operations, e.g. caesarean section, and for the relief of pain, e.g. labour pain or pain after an operation.

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

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

- If you are hypersensitive (allergic) to bupivacaine hydrochloride or any of the other ingredients of MACAINE HCl 0,5 % (listed in section 6)
- If you are allergic to any other local anaesthetics of the same class (such as lidocaine (lignocaine))
- If you have diseases of the brain or spine such as meningitis or polio
- 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 brain or spine tumours
- If you have tuberculosis of the spine
- If you have a skin infection at or 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 blood clotting or are on ongoing treatment for blood clots
- If you are under the age of 12 years
- If you are pregnant or breastfeeding (except when used during labour).

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

- If you have heart, kidney or liver problems. This is because your doctor may need to adjust the dose of MACAINE HCl 0,5 %
- 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) or low blood pressure
- If you have fluid in your lungs
- If you have blood poisoning (septicaemia).

If you are not sure if any of the above applies to you, talk to your doctor before you are administered MACAINE HCl 0,5 %.

Children

MACAINE 0,5 % HCl is not recommended for children younger than 12 years.

Other medicines and MACAINE HCl 0,5 % INJECTION

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

(This includes all complementary or traditional medicines.)

MACAINE 0,5 % HCl may interact with certain medicines.

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

- Other local anaesthetics, such as lidocaine (lignocaine)
- Medicines used to treat an uneven heartbeat (antidysrhythmics), such as amiodarone
- Medicines used to treat high blood pressure, including beta-blockers such as propranolol and calcium channel blockers such as amlodipine
- Medicines used to treat heartburn or stomach ulcers, such as cimetidine and ranitidine.

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 taking this medicine.

Safety in pregnancy and lactation, other for use in labour, has not been established.

Driving and using machines

MACAINE 0,5 % HCl may cause numbness and dizziness and may interfere with your ability to drive or use machinery. Ask your doctor when it would be safe to resume these activities.

MACAINE 0,5 % HCl contains sodium

MACAINE 0,5 % HCl contains 8,00 mg sodium (main component of table salt) per mL. This is equivalent to 0,4 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to receive MACAINE HCl 0,5 % INJECTION

You will receive MACAINE 0,5 % HCl through an injection. Your doctor will decide how much MACAINE 0,5 % HCl you should be given depending on the type of surgery and the duration of anaesthesia required. You will not be expected to give yourself MACAINE 0,5 % HCl. It will be given to you by a person who is qualified to do so.

If you receive more MACAINE 0,5 % HCl than you should

Since a healthcare provider will administer MACAINE 0,5 % HCl, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to receive MACAINE 0,5 % HCl

Since a healthcare provider will administer MACAINE 0,5 % HCl, it is unlikely that the dose will be missed.

4. Possible side effects

MACAINE 0,5 % HCl can have side effects.

Not all side effects reported for MACAINE 0,5 % HCl are included in this leaflet.

Should your general health worsen or if you experience any untoward effects

while taking MACAINE 0,5 % HCl, please consult your healthcare provider for advice.

If any of the following happens, stop receiving MACAINE 0,5 % HCl and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- Rash or itching
- Fainting.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Yellowing of the skin and eyes, also called jaundice
- Chest pain
- Changes in the way your heart beats, for example an unusually slow, fast or irregular heartbeat
- Difficulty breathing.

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

Tell your doctor if you notice any of the following:

Common side effects:

- Pins and needles
- Dizziness
- Slow heartbeat
- Changes in blood pressure (usually low blood pressure). This might make you feel dizzy or lightheaded
- High blood pressure
- Feeling sick (nausea) or being sick (vomiting)
- Problems passing water.

Uncommon side effects:

- Excitation, depression, and nervousness
- Fits (seizures)
- Numbness of the tongue or around the mouth
- Ringing in the ears or being sensitive to sound
- Loss of consciousness
- Shaking (tremors)
- Light headedness
- Difficulty speaking
- Twitching of your muscles
- Chill or fever
- Drowsiness
- 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
- Blurred vision, double vision
- Problems with your liver enzymes.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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 0,5 % HCL.

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 0,5 % HCl

Store at or below 25 °C

Protect from light.

Discard unused portion after initial use.

Store all medicines out of reach of children.

6. Contents of the pack and other information

What MACAINE 0,5 % HCl contains

The active substance is bupivacaine hydrochloride 5 mg per 1 ml

The other ingredients are sodium chloride, sodium hydroxide (pH adjuster), hydrochloric acid (pH adjuster) and water for injections.

What MACAINE 0,5 % HCl looks like and contents of the pack

A clear, colourless, aqueous solution.

A 10 mL single dose, clear neutral glass (USP Type 1) ampoule, or

A single dose, semi-rigid, transparent, low density polyethylene (LDPE) plastic ampoule.

Ten ampoules are packed in an outer carton.

Holder of Certificate of Registration

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MACAINE HCl 0,5 %
Injection

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