

1.3.2.3 PROPOSED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

**BUPIVACAINE HCl 0,5 % INJECTION WITH ADRENALINE 1:200 000 (as
bitartrate) ADCO injection**

**Bupivacaine hydrochloride 5 mg and adrenaline bitartrate 0,0091 mg (5
µg/mL adrenaline)**

Sugar free

**Read all of this leaflet carefully before you are administered BUPIVACAINE
HCl 0,5 % INJECTION WITH ADRENALINE 1:200 000 (as bitartrate) ADCO**

- 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 BUPIVACAINE HCl 0,5 % INJECTION WITH ADRENALINE 1:200 000
(as bitartrate) ADCO is and what it is used for

2. What you need to know before you are given BUPIVACAINE HCl 0,5 %
INJECTION WITH ADRENALINE 1:200 000 (as bitartrate) ADCO

3. How BUPIVACAINE HCl 0,5 % INJECTION WITH ADRENALINE 1:200 000
(as bitartrate) ADCO is given to you

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4. Possible side effects
5. How to store BUPIVACAINE HCl 0,5 % INJECTION WITH ADRENALINE
1:200 000 (as bitartrate) ADCO
6. Contents of the pack and other information

1. What BUPIVACAINE HCl 0,5 % INJECTION WITH ADRENALINE 1:200 000 (as bitartrate) ADCO is and what it is used for

BUPIVACAINE HCl 0,5 % INJECTION WITH ADRENALINE 1:200 000 (as bitartrate) ADCO contains two active ingredients:

- Bupivacaine, which belongs to a group of medicines called amide-type local anaesthetics, that work by producing a loss of feeling or sensation to one part of the body, and
- Adrenaline, which narrows the blood vessels at the site of injection which helps to keep the bupivacaine where it is needed for longer.

BUPIVACAINE HCl 0,5 % INJECTION WITH ADRENALINE 1:200 000 (as bitartrate) ADCO is used in adults and children above 12 years to stop pain happening or to provide pain relief. It can be used to:

- Numb parts of the body during surgery
- Relieve pain.

It may also be used to give prolonged relief of pain when it is injected around the spinal cord (epidural injection), e.g. as epidural injection in labour.

2. What you need to know before you are given BUPIVACAINE HCl 0,5 % INJECTION WITH ADRENALINE 1:200 000 (as bitartrate) ADCO

BUPIVACAINE HCl 0,5 % INJECTION WITH ADRENALINE 1:200 000 (as bitartrate) ADCO should not be administered to you:

- If you are hypersensitive (allergic) to bupivacaine or any other amide-type local anaesthetic, or to adrenaline, or any of the other ingredients of BUPIVACAINE HCl 0,5 % INJECTION WITH ADRENALINE 1:200 000 (as bitartrate) ADCO (listed in section 6)
- If you are to be injected in a vein of the hands or legs (Bier's block)
- If you suffer from the condition known as hyperthyroidism (when your body produces too much of the hormone thyroxine)
- If you have severe heart disease particularly if it is associated with an increased heart rate.

Because the solution contains adrenaline, which narrows the blood vessels, this injection should not be used in areas such as fingers, toes, ears, nose or penis, as the blood supply to these areas might become inadequate.

You should not be given this injection as an epidural if:

- You have bleeding inside the head (intracranial haemorrhage)
- You are suffering from any infection, disease or tumour of the brain or spinal cord
- You have an infection of the skin with pus at or near the site to be injected
- You have inadequate circulation of blood to the heart, sudden loss of blood or weakness of the heart that causes low blood pressure, a weak rapid pulse, sweating and confusion

- You have problems with the clotting of your blood or are taking any anticoagulant medicines (e.g. warfarin) that thin the blood
- You have increased pressure within the brain.

Warnings and precautions

Tell your doctor or health care provider before being given BUPIVACAINE HCl

0,5 % INJECTION WITH ADRENALINE 1:200 000 (as bitartrate) ADCO if:

- You have high blood pressure or problems with the circulation of blood to the brain or limbs
- You have a decrease in the amount of fluid circulating in your body causing symptoms such as sweating, mental confusion, dizziness or fainting (for example, due to dehydration or severe blood loss)
- You suffer from severe shock or low blood pressure
- You are overweight
- You are elderly (senile)
- You suffer from any heart problem, particularly if it affects the heart rate
- You suffer from any liver, severe kidney problems
- You have breathlessness or restriction to breathing from fluid or a large tumour in the abdomen
- You have excess fluid in the womb during pregnancy (hydramnios)
- You have a tumour of the ovary or the womb
- You have accumulation of fluid around the lungs
- You suffer from blood poisoning (septicaemia)
- You suffer from asthma
- You have diabetes

- You have an overactive thyroid gland (hyperthyroidism)
- You have a tumour of the adrenal glands called phaeochromocytoma
- You suffer from increased pressure in the eye (glaucoma)
- You have low potassium concentration in the blood
- You have excess calcium in the blood
- You suffer from cancer of the prostate
- You suffer from disorders/damage of the brain.

Children

Until further experience is gained, BUPIVACAINE HCl 0,5 % INJECTION WITH ADRENALINE 1:200 000 (as bitartrate) ADCO is not recommended for children younger than 12 years.

Other medicines and BUPIVACAINE HCl 0,5 % INJECTION WITH ADRENALINE 1:200 000 (as bitartrate) ADCO

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

(This includes all complementary or traditional medicines.)

BUPIVACAINE HCl 0,5 % INJECTION WITH ADRENALINE 1:200 000 (as bitartrate) ADCO reacts with a large number of medicines which can alter their effects. These medicines include:

- Lidocaine (lignocaine) and mexiletine (or any other amide-type medicine with local anaesthetic effect) for controlling the heart's rhythm
- Medicines which enhance the effects of the sympathetic system, as these may produce add-on effects with adrenaline

- Medicines to lower your blood pressure including alpha blockers e.g.
phentolamine
- Medicines used to treat irregular heart rhythm such as beta-blockers e.g.
propranolol
- Inhaled general anaesthetics, such as halothane
- Antihypertensive medicines such as adrenergic neurone blockers e.g.
guanethidine. Adrenaline opposes the effects of antihypertensives
resulting in an increase in blood pressure.
- Monoamine oxidase (MAO) inhibitors or tricyclic antidepressants e.g.
imipramine both used for depression, which may increase the effects
caused by adrenaline
- Medicines used to treat heart failure such as cardiac glycosides
- Medicines used to treat allergies such as antihistamines e.g.
diphenhydramine
- Medicines used to treat thyroid insufficiency such as thyroid hormones
- Medicines for Parkinson's disease (such as entacapone)
- Doxapram (a medicine which stimulates your breathing)
- Oxytocin (medicine which causes the womb to contract and may be used
in labour)
- Medicines used for pain and inflammation such as corticosteroids
- Medicines which help you to breathe e.g. aminophylline, theophylline
- Medicines used to treat increased blood sugar levels e.g. insulin, oral
hypoglycaemic medicines

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 BUPIVACAINE HCl 0,5 % INJECTION WITH ADRENALINE 1:200 000 (as bitartrate) ADCO.

Safe use of BUPIVACAINE HCl 0,5 % INJECTION WITH ADRENALINE 1:200 000 (as bitartrate) ADCO in pregnant women, other than those in labour, has not been established.

Bupivacaine should therefore not be given in early pregnancy unless the benefits are considered to outweigh the risks.

Bupivacaine is found in the breast milk in small amounts.

Driving and using machines

Certain areas of your body will be numb for about 2 – 4 hours after having this medicine. If this is likely to affect your ability to drive or use machinery you should wait for the effect to wear off. Consult your doctor whether it is safe for you to drive.

BUPIVACAINE HCl 0,5 % INJECTION WITH ADRENALINE 1:200 000 (as bitartrate) ADCO contains sodium metabisulphite:

This medicine contains sodium metabisulphite, a preservative. This may rarely cause severe allergic (hypersensitivity) reactions and wheezing.

3. How BUPIVACAINE HCl 0,5 % INJECTION WITH ADRENALINE 1:200 000 (as bitartrate) ADCO is given to you

BUPIVACAINE HCl 0,5 % INJECTION WITH ADRENALINE 1:200 000 (as bitartrate) ADCO is administered as an injection.

You will not be expected to give yourself BUPIVACAINE HCl 0,5 % INJECTION WITH ADRENALINE 1:200 000 (as bitartrate) ADCO. It will be given to you by a person who is qualified to do so.

If you receive more BUPIVACAINE HCl 0,5 % INJECTION WITH ADRENALINE 1:200 000 (as bitartrate) ADCO than you should

Since a healthcare provider will administer BUPIVACAINE HCl 0,5 % INJECTION WITH ADRENALINE 1:200 000 (as bitartrate) ADCO, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

4. Possible side effects

BUPIVACAINE HCl 0,5 % INJECTION WITH ADRENALINE 1:200 000 (as bitartrate) ADCO can have side effects.

Not all side effects reported for BUPIVACAINE HCl 0,5 % INJECTION WITH ADRENALINE 1:200 000 (as bitartrate) ADCO are included in this leaflet.

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

when given BUPIVACAINE HCl 0,5 % INJECTION WITH ADRENALINE 1:200 000 (as bitartrate) ADCO, please consult your healthcare provider for advice.

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

- 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 reaction to BUPIVACAINE HCl 0,5 % INJECTION WITH ADRENALINE 1:200 000 (as bitartrate) ADCO. 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:

- Chest pain
- Angina
- Changes in the way your heart beats, for example, if you notice it beating faster
- Difficulty breathing
- Signs of recurrent infections such as fever or sore throat
- Less urine than is normal for you
- Yellowing of the skin and eyes, dark urine and tiredness which may be symptoms of liver problems.

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

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Tell your doctor if you notice any of the following:

Frequent side effects:

- Pins and needles
- Dizziness
- Drooping of the upper eyelid, sunken eye or flushing on the affected side of the face (Horner's syndrome) are most commonly experienced in pregnant women
- Problems passing urine.

Less frequent side effects:

- Decrease in the number of red blood cells (anaemia)
- A condition in which a higher-than-normal amount of methaemoglobin is found in the blood (methaemoglobinaemia). Methaemoglobin is a form of haemoglobin that cannot carry oxygen
- Drowsiness
- Headache
- Complete or partial loss of muscle function
- Loss of bladder control or failure to control bowel movements
- Difficulty, slowed or stopped breathing
- Loss of consciousness
- Blurred vision (visual disturbances)
- Uncontrollable involuntary muscle movement (tremor)
- Ringing in the ears (tinnitus)
- Double vision

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- Uneven heartbeat or stopped heartbeat. This could be life threatening
- Constipation
- Feeling of being sick (vomiting)
- Numbness of the lips and mouth
- Back pain
- Sexual dysfunction
- Fever
- A significant drop in body temperature

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 BUPIVACAINE HCl 0,5 % INJECTION WITH ADRENALINE 1:200 000 (as bitartrate) ADCO.

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 BUPIVACAINE HCl 0,5 % INJECTION WITH ADRENALINE 1:200 000 (as bitartrate) ADCO

Store at or below 25 °C

Protect from light

Store all medicines out of reach of children

6. Contents of the pack and other information

What BUPIVACAINE HCl 0,5 % INJECTION WITH ADRENALINE 1:200 000 (as bitartrate) ADCO contains

The actives are: bupivacaine hydrochloride 5 mg and adrenaline bitartrate 0,0091 mg (5 µg/mL adrenaline) per 1 mL.

The other ingredients are: sodium metabisulphite, monothioglycerol, ascorbic acid, edetate calcium disodium, sodium chloride, sodium lactate solution, sodium hydroxide (for pH adjustment), hydrochloric acid (for pH adjustment), water for injection.

What BUPIVACAINE HCl 0,5 % INJECTION WITH ADRENALINE 1:200 000 (as bitartrate) ADCO looks like and contents of the pack

A clear, colourless solution.

A pack of 2 shrink-wrapped cartons, each containing 5 x 20 mL clear, one-point cut (OPC) glass ampoules.

The ampoules are packed into a white EPS tray box.

BUPIVACAINE HCl 0,5 % INJECTION WITH ADRENALINE
1:200 000 (as bitartrate) ADCO
Injection

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