

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

CARBOCAINE 3 % DENTAL injection

Mepivacaine hydrochloride

Glucose free

Read all of this leaflet carefully before you are given CARBOCAINE 3 % DENTAL

- 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.
- CARBOCAINE 3 % DENTAL has been prescribed for you personally.

What is in this leaflet

1. What CARBOCAINE 3 % DENTAL is and what it is used for
2. What you need to know before you use CARBOCAINE 3 % DENTAL
3. How CARBOCAINE 3 % DENTAL will be used
4. Possible side effects
5. How CARBOCAINE 3 % DENTAL is stored
6. Contents of the pack and other information

1. What CARBOCAINE 3 % DENTAL is and what it is used for

The active ingredient in CARBOCAINE 3 % DENTAL is mepivacaine hydrochloride.

Each 1,8 ml of CARBOCAINE 3 % DENTAL contains mepivacaine hydrochloride 54 mg.

CARBOCAINE 3 % is a local anaesthetic, which numbs a particular region to prevent or minimize

pain.

CARBOCAINE 3 % DENTAL is used for dental extractions and conservative dental procedures in adults, adolescents and children above 4 years of age (ca. 20 kg in body weight). It contains the active substance mepivacaine hydrochloride and belongs to the group of nervous system anaesthetics.

2. What you need to know before you decide whether CARBOCAINE 3 % DENTAL should or should not be administered to you:

Do not use CARBOCAINE 3 % DENTAL:

- If you are hypersensitive (allergic) to mepivacaine hydrochloride or any of the other ingredients of CARBOCAINE 3 % DENTAL.
- In children below 4 years old (ca. 20 kg in body weight)
- If you have porphyria (group of disorders that can cause nerve or skin problems)
- If you have an atrioventricular conduction (impairment of the electrical continuity between the atria and ventricles of the heart), not compensated by a pacemaker.
- If you have epilepsy not controlled by any appropriate treatment.

Warnings and precautions

Your doctor will need to be aware of the following:

Special care should be taken with CARBOCAINE 3 % DENTAL

- Do not autoclave (heated container using high pressures and high temperature to sterilize).
- If you are pregnant, because safe use of CARBOCAINE 3 % DENTAL has not been established in respect to fetal development.
- If you have myasthenia gravis (weakness of certain muscles).
- Do not chew gum or food as long as there is no sensitivity in the injected area, because you can bite your lips, cheeks, mucosa or tongue.
- Do not give to children under 4 years, because anaesthetic procedures are not suitable for children under 4.

- If you are an athlete, CARBOCAINE 3 % DENTAL contains an active substance that can give a positive reaction to anti-doping tests.
- If you use CARBOCAINE 3 % DENTAL in your practice, resuscitation equipment, oxygen and other resuscitation drugs should be available immediately.
- Use the lowest dosage that results in effective anaesthesia to avoid high plasma levels.
Repeated doses of mepivacaine may cause significant increases in blood levels with each repeat dose due to slow accumulation of the drug or its metabolites. Tolerance to elevated blood levels varies from patient to patient.
Lower doses proportional to age and physical conditions should be given to children, old or ageing people, acutely ill patients or when your body or mind is becoming gradually weaker.
- After each local anaesthetic injection, the patient's cardiovascular and respiratory vital signs and state of consciousness must be monitored.
- Signs of central nervous system toxicity is restlessness, anxiety, tinnitus, dizziness, blurred vision, tremors, depression or drowsiness.
- Signs and symptoms of depressed cardiovascular function may commonly result from a vasovagal reaction, particularly if the patient is in an upright position.
- Dose should be lowered if you have liver problems or renal disease.
- If there is inflammation and/or sepsis in the area of the injection site, because it may lead to a reduced effect and increased absorption.
- If you use anti-coagulants (inhibitors of the coagulation of the blood) such as aspirin, heparin or warfarin.
- If you have hypoxia (low amount of oxygen reaching the tissues), hyperkalemia (high potassium) and acidosis (too much acid in the body fluids).
- If you have a repolarization disorder, such as QT prolongation.
- If you have epilepsy, heart problems or respiratory problems.
- The product is for single use on one patient during one treatment only. Any remaining contents should be discarded.

Other medicines and CARBOCAINE 3 % DENTAL

Always tell your healthcare provider if you are taking any other medicine(s). (This includes all complementary or traditional medicines).

Do not use cimetidine, because the serum levels of amide anaesthetics will increase.

Medicines used to reduce patient apprehension (e.g. sedatives). In this case, the dosage of anaesthetic should be reduced.

Do not use with other local anaesthetics;

Do not use medicines used to stabilize heartbeat (antiarrhythmics);

Do not use Cytochrome P450 1A2 inhibitors;

Do not medicines used to treat hypertension (propranolol).

CARBOCAINE 3 % DENTAL with food

Avoid eating, included chewing-gum, until normal sensation is restored because there is a risk that you may bite your lips, cheeks or tongue, especially in children.

Pregnancy, breastfeeding and fertility

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 using this medicine.

Safety in pregnancy and breastfeeding has not been established.

Driving and using machinery:

CARBOCAINE 3 % DENTAL may have an influence on the ability to drive and use machines.

Dizziness (including loss of balance, vision disorder and extreme tiredness) may occur. If you experience these symptoms you should not drive or use machinery until any such symptoms have

completely resolved.

3. How to use CARBOCAINE 3 % DENTAL

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself CARBOCAINE 3 % DENTAL. It will be given to you by a person who is qualified to do so.

The dose used depends on the area to be anaesthetized (makes you unable to feel pain), blood supply and neurons to the area and individual tolerance.

The average dose of one dental cartridge will be enough, but this dose may be doubled if necessary.

The maximum adult dose should not be more than 400 mg mepivacaine hydrochloride (7 mg/kg) at one time and the total dose should not be more than 1 g over a twenty-four hour period.

The recommended dose should not be exceeded.

Any unused portion of the dental cartridge must be discarded.

Resuscitative equipment and emergency medicines should be available when any anaesthetic is used.

The diaphragm of the CARBOCAINE 3 % DENTAL injection cartridge should be disinfected before needle puncture.

Only the metal cap should be put in undiluted isopropyl alcohol or 70 % ethyl alcohol for at least fifteen minutes. Only enough cartridges for one day's use should be stored in the alcohol.

If you have been given more CARBOCAINE 3 % DENTAL than you should have received

Since a healthcare provider will administer CARBOCAINE 3 % DENTAL, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you have been given more CARBOCAINE 3 % DENTAL than you should, it may lead to symptoms that correspond to possible side effects, such as, cardio-respiratory arrest (impairment of the electrical pathways and specialised muscle fibres that conduct impulses through the heart), convulsions and sleepiness. Treatment is symptomatic and supportive. Resuscitative equipment and emergency medicines should always be immediately available, as symptomatic treatment is

recommended.

Acute emergencies from CARBOCAINE 3 % DENTAL are generally because of high plasma levels due to more CARBOCAINE 3 % DENTAL given, than necessary.

The symptoms are dose-dependent and may progress in severity from neurological symptoms to vascular, respiratory, and finally cardiac toxicity.

Symptoms may include lightheadedness, dizziness, restlessness, hearing and visual disturbances, drowsiness, disorientation, slurred speech, shivering, muscle twitching, tremors of the face, fingers and toes, generalized seizures and respiratory arrest. Hypoxia (low levels of oxygen reaching the tissues) and hypercapnia (high levels of carbon dioxide in the blood) occur rapidly following convulsions due to increased muscular activity, together with the interference with normal respiration. In severe cases, you may stop breathing. Acidosis (high levels of acid in the body fluids) increases the toxic effects of local anaesthetics.

Effects on the cardiovascular system may be seen in severe cases of overdosage. Hypotension (low blood pressure), bradycardia (slow heart rate), arrhythmia (irregular heartbeat) and cardiac arrest may occur as a result of high systemic concentrations, with potentially fatal outcome.

4. Possible side effects

CARBOCAINE 3 % DENTAL can have side effects.

Not all side effects reported for CARBOCAINE 3 % DENTAL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving CARBOCAINE 3 % DENTAL, please consult your healthcare provider for advice.

If any of the following happens, stop using CARBOCAINE 3 % DENTAL, and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Hypersensitivity
- Anaphylactic / anaphylactoid reaction (life-threatening allergic reaction)

- Swelling of the face, lips, tongue, throat, larynx (passage to the lungs) and around the eyes, which may cause difficulty in swallowing or breathing,
- Bronchospasm / asthma (spasm of bronchial smooth muscle, producing narrowing of the bronchi)
- Rash or itching,
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to CARBOCAINE 3 % DENTAL. 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:

Less frequent side effects:

- Neuropathy (disease or dysfunction of one or more peripheral nerves, typically causing numbness or weakness)
- Neuralgia (pain along the course of a nerve, especially in the head or face-)
- Tremors
- Central nervous system depression is a physiological state that can result in a decreased rate of breathing, decreased heart rate, and loss of consciousness possibly leading to coma or death
- Convulsions (including tonic clonic seizure)
- Feeling of passing out
- Confusional state
- Disorientation
- Myocardial depression (dysfunction of both the left and right sides of the heart)
- Cardiac arrest (a sudden, sometimes temporary, cessation of the heart's functioning)
- Bradyarrhythmia (A disturbance of the heart's rhythm resulting in a rate under 60 beats per minute)

- Bradycardia (abnormal slow heart action)
- Tachyarrhythmia (heart rhythm with a ventricular rate of 100 beats/min or greater)
- Angina pectoris (condition marked by severe pain in the chest, often also spreading to the shoulders, arms, and neck, owing to an inadequate blood supply to the heart)
- Conduction disorders (electrical system that makes your heartbeat and controls its rate and rhythm)
- Tachycardia (rapid heart rate)
- Palpitations (fast beating, fluttering or pounding heart)
- Dysrhythmia (abnormality in the physiological rhythm of the heart)
- Arrhythmias (electrical impulses that coordinate your heartbeats don't work properly)
- Hypotension (low blood pressure)
- Hypertension (high blood pressure)
- Respiratory depression (is a breathing disorder characterized by slow and ineffective breathing)
- Bradypnoea (slow breathing rate)
- Apnoea (temporary cessation of breathing, especially during sleep).
- Yawning (involuntarily open one's mouth wide and inhale deeply)
- Dyspnoea (difficult or laboured breathing).

Side effects with unknown frequency:

- Methaemoglobinaemia (is a blood disorder in which an abnormal amount of methemoglobin is produced)
- Vasodilation (dilatation of blood vessels, which decreases blood pressure)
- Hypoxia (low amount of oxygen reaching the tissues)
- Hypercapnia (too much carbon dioxide (CO₂) in the blood)
- Chest pain

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

Less frequent side effects:

- Paresthesia (i.e. burning, prickling, itching, tingling, local sensation of heat or cold, with no apparent physical cause) of oral and perioral (tissue around the mouth) structures
- Hypoesthesia / numbness of the tongue and perioral region
- Dysesthesia (Abnormal painful, burning, itchy or restrictive sensation) (oral and perioral)
- Dysgeusia (e.g., taste metallic, taste distorted)
- Ageusia (loss or impairment of the sense of taste)
- Dizziness (light-headedness)
- Vertigo (loss of balance)
- Speech disorder
- Restlessness
- Agitation (state of anxiety or nervous excitement)
- Balance disorder
- Visual impairment (decrease in the ability to see to a certain degree that causes problems not fixable by usual means, such as glasses)
- Blurred vision (lack of sharpness of vision)
- Accommodation disorders (is a problem with focusing, particularly at near)
- Nausea
- Vomiting
- Gingival / oral mucosal exfoliation (sloughing) / ulceration

- Muscle twitching
- Chills (shivering)
- Local swelling
- Injection site swelling

Side effects with unknown frequency:

- Anxiety / Nervousness
- Euphoric mood (feeling of great happiness and excitement)
- Apprehension (fear that something bad or unpleasant will happen)
- Sleepiness
- Nystagmus (rapid involuntary movements of the eyes)
- Horner's syndrome (combination of signs and symptoms caused by the disruption of a nerve pathway from the brain to the face and eye on one side of the body)
- Eyelid ptosis (upper eyelid droops over the eye)
- Enophthalmos (posterior displacement of the eye)
- Diplopia (double vision)
- Amaurosis (partial or total blindness without visible change in the eye, typically due to disease of the optic nerve, spinal cord, or brain)
- Blindness
- Mydriasis (dilation of the pupil of the eye)
- Miosis (excessive constriction of the pupil of the eye)
- Ear discomfort
- Ringing in the ears
- Increased sensitivity to normal environmental sounds
- Dysphonia (Hoarseness – abnormal voice)
- Stomatitis, glossitis, gingivitis (inflammation of the mucous membrane of the mouth, tongue)

and gums)

- Oedema (The build-up of fluid causes affected tissue to become swollen)
- Fatigue (tiredness or lack of energy), asthenia (weakness)
- Feeling hot
- Injection site pain

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 “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of CARBOCAINE 3 % DENTAL

5. How CARBOCAINE 3 % DENTAL is stored

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 CARBOCAINE 3 % DENTAL contains

The active substance is mepivacaine hydrochloride. There is 54 mg mepivacaine hydrochloride in each 1,8 ml dental cartridge.

The other ingredients are sodium chloride.

What CARBOCAINE 3 % DENTAL looks like and contents of the pack

CARBOCAINE 3 % DENTAL cartridges are clear glass cartridges containing a clear, colourless

solution, free of particulate matter. The glass cartridge is printed with the product name.

CARBOCAINE 3 % DENTAL is available in 1,8 ml dental cartridges in cans of 100 cartridges and 10 × 10 blisters of 1,8 ml dental cartridges packed into a cardboard carton.

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