**Buloc 0.25 Injection 20ml**

**MANUFACTURER/ MARKETER**

Celon Laboratories Ltd

**SALT COMPOSITION**

Bupivacaine Hcl 50mg/20mL

**Storage**

Store below 30°C

**INTRODUCTION**

BULOC 0.25 contains Bupivacaine which belongs to the group of medicines called Local anesthetic agents. It is used to cause numbness of body parts during surgery (including dental surgery) in both adults and in children (aged above 12 years). It can also be used as an analgesic to provide pain relief in adults, children and in infants (aged above 1 year).

Bupivacaine is a long-acting local anesthetic agent. It decreases pain sensation and causes temporary numbness at certain regions of the body by blocking the transfer of pain signals from the peripheral part of the body to the brain.

BULOC 0.25 will be given to you only by a trained anesthesiologist. It can be administered locally to the region where loss of sensation (numbness) is required or can be administered around the spinal cord or a nerve to causes numbness during surgeries (caesarean section or other major surgeries) or to provide pain relief during painful conditions (such as labor pain or post-operative pain).

Although bupivacaine is used prior to caesarean section or during labor pain, higher doses of bupivacaine are currently not recommended for epidural anesthesia (spinal anesthesia given during childbirth) due to increased risk of side effects. Also, it should not be used to anesthetize cervical or vaginal regions (obstetrical paracervical block) in women undergoing labor.

BULOC 0.25 should not be administered in the veins for pain block (Bier’s block). It is also not suitable for use in patients having any severe infections, bleeding problems or any problems in blood circulation.

Before receiving BULOC 0.25, inform your doctor if you have any liver, kidney, or heart problems. You must also inform your doctor if you have tumors in the body or low blood volume due to loss of fluids from the body before receiving BULOC 0.25.

Inform your doctor before receiving BULOC 0.25 if you are pregnant or breastfeeding. It should be used with caution in pregnant women having high blood pressure or excess fluid in the womb. The most common side effects of receiving BULOC 0.25 are nausea, vomiting, slow heart rate, dizziness, tingling sensation, and difficulty to pass urine. Consult your doctor if any of these side effect troubles you.

USES OF BULOC 0.25

It is used to:

* Cause numbness of body parts during surgery in both adults and in children (aged above 12 years)
* Provide pain relief in adults, children and in infants
* HOW BULOC 0.25 WORKS
* BULOC 0.25 reduces pain sensation and causes numbness of body parts. It contains bupivacaine which acts by blocking the flow of certain ions (sodium ions) through the nerves that causes pain sensation. As a result, it limits the transfer of pain signals from the peripheral part of the body (i.e., face, hands, legs, abdomen, pelvis) to the brain which leads to loss of sensation.
* DIRECTIONS FOR USE
* BULOC 0.25 will be given to you only by a doctor or by a trained anesthesiologist. Your doctor/ anesthesiologist will decide the correct dose and site of administration for you depending upon your age, body weight, health condition and type of nerve block which is required to provide anesthesia or pain relief.
* It can be administered locally to the region where loss of sensation (numbness) is required or can be administered around the spinal cord or a nerve to causes numbness during surgeries (caesarean section or other major surgeries) or to provide pain relief during painful conditions (such as labor pain or post-operative pain).

**SIDE EFFECTS OF BULOC 0.25**

**COMMON**

* Low blood pressure causing dizziness or lightheadedness
* Nausea, vomiting
* Tingling or pricking sensation (pins and needles)
* Slow heartbeat
* Difficulty in passing urine
* Horner’s syndrome (drooping of upper eyelids, flushing of the face and swollen eyes)

UNCOMMON

* Difficulty in speaking
* Numbness of tongue
* Blurred vision
* Loss of consciousness
* Shivering
* Twitching of muscles
* Ringing sensation in the ears
* Sensitivity to sound
* Seizure/ fits

RARE

* Loss of sensation or body movements
* Nerve damage, muscle pain
* Inflammation or injury of the spine cord

Contact your doctor immediately if you experience any of the following side effects after receiving BULOC 0.25:

* Severe allergic reactions (such as skin rash, severe itching of the skin with raised lumps, blisters in the skin, swelling of the face, lips, tongue and/or throat with difficulty in breathing or swallowing)
* Uneven heartbeat
* HOW TO MANAGE SIDE EFFECTS
* **Dizziness:**
* Avoid standing or walking after surgery. Try to rest and relax. Get enough sleep. Consult your doctor if you continue to feel dizzy for a prolonged period.
* **Blurred vision:**
* Close your eyes and relax. Do not strain your eyes. Do not move from your place or perform any physical activity while your vision is blur. Consult your doctor if you experience blurred vision for a prolonged period.

WARNING & PRECAUTIONS

PREGNANCY

BULOC 0.25 should be used in pregnant women only if it is considered necessary by the physician. It should be used with extreme caution in pregnant women who have excess fluid buildup in their womb or have a very high blood pressure during their pregnancy. Therefore, inform your doctor if you are pregnant or think you may be pregnant before receiving BULOC 0.25.

BREASTFEEDING

BULOC 0.25 should be used in breastfeeding women only if it is considered necessary by the physician. Therefore, inform your doctor before receiving it.

DRIVING AND USING MACHINES

Do not drive or operate any heavy tools or machines if your ability is affected by BULOC 0.25.

ALCOHOL

Avoid consumption of alcohol before receiving BULOC 0.25.

KIDNEY

BULOC 0.25 used to be used with caution in patients with kidney diseases. Therefore, inform your doctor before receiving it.

LIVER

BULOC 0.25 used to be used with caution in patients with moderate to severe liver diseases. Therefore, inform your doctor before receiving it.

ALLERGY

Inform your doctor before receiving BULOC 0.25 if you are allergic to bupivacaine or to any other local anesthetics (such as ropivacaine or lidocaine).

LUNGS

BULOC 0.25 used to be used with caution in patients who have fluid-buildup in the lungs (pulmonary edema). Therefore, inform your doctor before receiving it.

HEART DISEASE

BULOC 0.25 should be used with caution in patients with heart diseases (such as heart block, slow heartbeat, or poor blood supply to the heart). Therefore, inform your doctor before receiving it.

OTHERS

BULOC 0.25 is not recommended for use if you:

* Require Bier’s block (administering local anesthetics in the veins)
* Require obstetrical paracervical block (anesthesia given in the vaginal region during labor pain)
* Have any inflammation or infection next to the site of administration
* Have problems in blood circulation
* Have problems in blood clotting
* Have any infection/disease or tumor of the brain or spinal cord
* Have intracranial bleeding (bleeding inside the skull)
* Have increased pressure within the brain

Inform your doctor, before receiving BULOC 0.25 if you:

* Suffer from severe shock or low blood pressure
* Have a large tumor in the abdomen, ovary, uterus or in the spinal cord
* Have septicemia (poisoning of blood)
* Have accumulation of excess fat in the body
* Have low blood volume (symptoms such as sweating, mental confusion, dizziness or fainting) due to dehydration or severe blood loss

**Use in pediatrics:**

BULOC 0.25 should be used with caution in infants (aged above 1 year), children and in adolescents (aged 12 years or above). Your doctor will decide the suitable dose for your child based on their age, body weight and health condition. BULOC 0.25 is not recommended for use in infants aged below 1 year due to lack of safety data.

**Use in geriatrics:**

BULOC 0.25 should be used with caution in elderly patients who generally have a very weak health condition. Careful monitoring is required in such patients.

INTERACTIONS

**A. Drug-Drug Interaction:**

Before receiving BULOC 0.25, inform your doctor if you are taking any of the following medicines such as:

* Other local anesthetics (used to induce numbness temporarily) Ex. lidocaine, ropivacaine
* Medicines used to treat heart problems such as abnormal heart rhythm (Ex. mexiletine, quinine, tocainide), or hypertension (Ex. verapamil, enalapril, ramipril)
* Anticoagulants (used for blood thinning) Ex. aspirin, warfarin etc.
* Beta-blockers (used to control high blood pressure) Ex. atenolol, propranolol
* Medicines used to treat depression such as monoamine oxidase inhibitors (isocarboxazid, tranylcypromine, selegiline) or tricyclic antidepressants (amitriptyline, imipramine)
* Ergot alkaloids (used to treat migraine headache) Ex. ergotamine
* Nitrates (used to treat angina) Ex. nitroglycerin, nitric oxide
* Antineoplastic agents (used to treat cancer) Ex. cyclophosphamide, hydroxyurea, isofamide, rasburicase
* Antibiotics (used to treat bacterial infections) Ex. nitrofurantoin, dapsone, para-aminosalicylic acid, sulfonamides (Ex. sulfasalazine)
* Antimalarials (used to treat malaria) Ex. chloroquine, primaquine
* Medicines used to treat epilepsy (Ex. phenytoin, sodium valproate, phenobarbital)
* Paracetamol (a medicine used for fever and body pains)
* Metoclopramide (a medicine used to treat nausea and vomiting)

**Overdosage:**

BULOC 0.25 will be administered to you only by a doctor or a nurse in a hospital, and so it is unlikely to receive an overdose. However, consult your doctor or nurse if you experience any unusual symptoms. Symptoms of overdosage might include severe breathing difficulty, abnormal heartbeat, loss of taste, chest pain or discomfort, tingling sensation of the skin, increased thirst, ringing sensation in the ears or sensitivity to sound.

SYNOPSIS

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| **Drug** | : | Bupivacaine |
| **Pharmacological Category** | : | Local anesthetic agent |
| **Therapeutic Indication** | : | Local anesthesia (numbness), Pain relief |
| **Dosage Forms** | : | Injection |

MORE INFORMATION

* Keep BULOC 0.25 out of reach of children
* Store BULOC 0.25 at room temperature

FAQs ABOUT BULOC 0.25

**How long will it take for BULOC 0.25 to induce numbness?**

It may take around 5 minutes for BULOC 0.25 to create numbness of body parts. However, this period may vary from person-to-person based on the dose and amount of the BULOC 0.25 that is administered to you.

**Is BULOC 0.25 a narcotic medicine?**

No. BULOC 0.25 is not a narcotic. It is a local anesthetic agent which is used to create loss of sensation (numbness) in certain body parts following administration.

**Can BULOC 0.25 affect blood pressure?**

Yes. BULOC 0.25 may cause changes in blood pressure (high or low blood pressure) and so if you experience any unusual symptoms like feeling extremely dizzy or lightheaded after receiving BULOC 0.25 consult your doctor.

**What are the common side effects of BULOC 0.25?**

The most common side effects of receiving BULOC 0.25 are nausea, vomiting, slow heart rate, dizziness, tingling sensation, and difficulty to pass urine. Consult your doctor if any of these side effect troubles you.

**What are the symptoms that could appear if I received excessive amount of BULOC 0.25?**

BULOC 0.25 will be administered to you only by a doctor or a nurse in a hospital, and so it is unlikely to receive an overdose. However, consult your doctor or nurse if you experience any unusual symptoms like severe breathing difficulty, abnormal heartbeat, loss of taste, chest pain or discomfort, tingling sensation of the skin, increased thirst, ringing sensation in the ears or sensitivity to sound.

**Can BULOC 0.25 be used in children?**

Yes. BULOC 0.25 is used in children and in adolescents (aged between 1-18 years) only if it is considered necessary by the physician. It is not recommended for use in infants aged below 1 year due to lack of safety data.

**Can BULOC 0.25 cause nerve damage?**

Yes. BULOC 0.25 may cause nerve damage when administered in excess amount. Therefore, inform your doctor if you experience signs of nerve damage (such as tingling in the hands and feet) while receiving BULOC 0.25.

**Is BULOC 0.25 safe for use in pregnant women?**

BULOC 0.25 should be used in pregnant women only if it is considered necessary by the physician. It should be used with extreme caution in pregnant women who have excess fluid buildup in their womb or have a very high blood pressure during their pregnancy. Therefore, inform your doctor if you are pregnant or think you may be pregnant before receiving BULOC 0.25.