

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

SENSORCAINE®

Bupivacaine hydrochloride Solution

SENSORCAINE® with Epinephrine

Bupivacaine hydrochloride and Epinephrine Solution

Read this carefully before you start taking **SENSORCAINE** and **SENSORCAINE with Epinephrine** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **SENSORCAINE** and **SENSORCAINE with Epinephrine**.

What is SENSORCAINE and SENSORCAINE with Epinephrine used for?

SENSORCAINE / **SENSORCAINE with Epinephrine** are used to numb (anaesthetise) part of the body during surgery and also for pain relief. **SENSORCAINE** / **SENSORCAINE with Epinephrine** can be used to:

- numb the area of the body where surgery is to be performed.
- provide pain relief in labour.
- provide pain relief after surgery.
- provide pain relief after an injury.

How does SENSORCAINE and SENSORCAINE with Epinephrine work?

SENSORCAINE / **SENSORCAINE with Epinephrine** work by temporarily blocking the nerves in the area it is injected so you do not feel pain, heat or cold. This makes the area numb and relieves pain. You may still feel pressure and touch. In many cases the nerves to the muscles in the area will also be blocked. This can cause temporary weakness or paralysis.

What are the ingredients in SENSORCAINE and SENSORCAINE with Epinephrine?

Medicinal ingredients:

SENSORCAINE: bupivacaine hydrochloride.

SENSORCAINE with Epinephrine: bupivacaine hydrochloride, epinephrine bitartrate.

Non-medicinal ingredients:

SENSORCAINE contains sodium chloride, sodium hydroxide and/or hydrochloric acid and water for injection.

SENSORCAINE with Epinephrine contains sodium chloride, sodium hydroxide and/or hydrochloric acid, sodium metabisulphite and water for injection.

SENSORCAINE and SENSORCAINE with Epinephrine comes in the following dosage forms:

SENSORCAINE is available as a solution: 0.25% (2.5 mg/mL) and 0.5% (5 mg/mL).

SENSORCAINE with Epinephrine is available as SENSORCAINE 0.25% (2.5 mg/mL) or 0.5% (5 mg/mL) with epinephrine (as bitartrate) 5 mcg/mL (1:200,000).

Do not use SENSORCAINE and SENSORCAINE with Epinephrine if you are allergic (hypersensitive) to:

- bupivacaine hydrochloride
- epinephrine bitartrate
- any other “-caine” type anaesthetics
- sodium metabisulfite
- any of the non-medicinal ingredients in the product, or component of the container (see above)

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take SENSORCAINE and SENSORCAINE with Epinephrine. Talk about any health conditions or problems you may have, including if you:

- have heart problems
- have high blood pressure
- have problems with the blood flow to your brain
- have Peripheral Vascular Disease or problems with your blood circulation
- have thyroid problems
- have diabetes
- have liver problems
- have kidney problems
- have asthma
- are pregnant
- are breastfeeding or planning to breastfeed

Other warnings you should know about:

Driving and Using Machines: SENSORCAINE / SENSORCAINE with Epinephrine can affect your level of alertness, your reactions and your coordination. You should use caution driving and

when operating tools or machinery on the day you receive SENSORCAINE / SENSORCAINE with Epinephrine.

Liver Injury: Serious cases of liver injury including drug-induced liver injury (DILI), liver failure and increased liver enzymes have been reported in people being treated with bupivacaine, the medicinal ingredient in SENSORCAINE / SENSORCAINE with Epinephrine. This is more likely to happen in people being treated with SENSORCAINE / SENSORCAINE with Epinephrine repeatedly or for a long time. These side effects happened in people with and without a history of previous liver problems. For more information and this and other serious side effects, see the **Serious side effects and what to do about them** table, below.

Joint Damage: Because of the potential for irreversible joint damage, SENSORCAINE should not be used to treat pain following joint surgery.

Use in Children:

- SENSORCAINE / SENSORCAINE with Epinephrine is not to be used in children under 2 years of age.
- It is not known if SENSORCAINE / SENSORCAINE with Epinephrine is safe and effective in children 2 - 12 years of age. SEONSORCAINE / SEONSORCAINE with Epinephrine should only be used in this age group if the benefit outweighs the risk.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with SENSORCAINE and SENSORCAINE with Epinephrine:

- other local anaesthetics, such as lidocaine, ropivacaine, mepivacaine, prilocaine, chloroprocaine
- medicines used to treat heartburn, such as cimetidine and ranitidine
- sedatives

Additional medicines that may interact with SENSORCAINE with Epinephrine include:

- medicines used to treat depression such as monoamine oxidase (MAO) inhibitors, triptyline, imipramine
- ergot-type medicines used to treat migraines
- phenothiazines used to treat mental health problems
- medicines used to treat high blood pressure, such as propranolol

How to take SENSORCAINE and SENSORCAINE with Epinephrine:

Usual dose:

Your healthcare professional will decide how much SENSORCAINE / SENSORCAINE with Epinephrine to give you.

Overdose:

If you think you, or a person you are caring for, have been given too much SENSORCAINE or SENSORCAINE with Epinephrine contact a healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

The first signs that too much SENSORCAINE / SENSORCAINE with Epinephrine has been given are: lightheadedness, numbness of the lips and around the mouth, numbness of the tongue, hearing disturbances, ringing in the ears, and visual disturbances. Symptoms that are more serious include speech problems, muscle twitching and tremors. Tell your healthcare professional immediately if you notice any of these symptoms.

In the case of a serious overdose or a misplaced injection, trembling, seizures or unconsciousness may occur

What are possible side effects from using SENSORCAINE and SENSORCAINE with Epinephrine?

These are not all the possible side effects you may have when taking SENSORCAINE / SENSORCAINE with Epinephrine. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- feeling sick, nausea
- vomiting
- dizziness

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON Low Blood Pressure: dizziness, fainting, lightheadedness May occur when you go from lying or sitting to standing up.		X	
COMMON Slow heart beat		X	
Trouble urinating, unable to pass urine		X	
High Blood Pressure: headache, fatigue, vision problems, irregular heart beat		X	
RARE Allergic Reaction: rash, hives, itching, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing, fast heart rate, sneezing, nausea, vomiting, fainting, sweating			X
Double vision		X	
Irregular heart beat or heart skips a beat (heart palpitations)			X
Nerve Problems: nerve injury, paralysis, numbness or tingling of the extremities, weakness		X	
Central Nervous System Problems: restlessness, anxiety, dizziness, ringing in the ears, blurred vision, tremors, seizures or fits			X

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Heart Attack or Cardiovascular Collapse: chest pain or tightness, pain spreading to the neck, jaw or back, nausea, indigestion, shortness of breath, cold sweat, fatigue, lightheadedness, fast heart beat, fainting			X
Liver Injury (including Drug Induced Liver Injury, liver failure): yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite			X

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

<p>Reporting Side Effects</p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> • Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or • Calling toll-free at 1-866-234-2345. <p><i>NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.</i></p>
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Storage:

Your healthcare professional or the hospital will store SENSORCAINE / SENSORCAINE with Epinephrine.

Keep out of reach and sight of children.

If you want more information about SENSORCAINE / SENSORCAINE with Epinephrine:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website (www.aspenpharma.ca), or by calling 1-844-330-1213.

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