

PART III: CONSUMER INFORMATION

MARCAINE[®]

(Bupivacaine Hydrochloride Injection USP)

MARCAINE[®] SPINAL

(Bupivacaine Hydrochloride in Dextrose Injection USP)

MARCAINE[®] E

(Bupivacaine Hydrochloride and Epinephrine Injection USP)

This leaflet is part III of a three-part "Product Monograph" published when Marcaine, Marcaine Spinal and Marcaine E were approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Marcaine, Marcaine Spinal and Marcaine E. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

MARCAINE, MARCAINE SPINAL and MARCAINE E are used to anesthetize part of the body for surgical operations and also for pain relief, and can be used:

- to anesthetize the area of the body where surgery is to be performed;
- to provide pain relief in labour and after surgery or acute injury.

What it does:

MARCAINE, MARCAINE SPINAL and MARCAINE E act by temporarily preventing the nerves in the injected area from transmitting sensations of pain, heat or cold. However, you may still experience sensations such as pressure and touch. In this way the nerve(s) is anesthetized/ numbed in the part of the body, which will be subjected to surgery. In many cases this means that the nerves to the muscles in the area will also be blocked, causing temporary weakness or paralysis.

When it should not be used:

MARCAINE, MARCAINE SPINAL and MARCAINE E should not be used in patients who are allergic to:

- bupivacaine hydrochloride
- any other "-caine" type anesthetics
- any of the non-medicinal ingredients in the product (see **What the non-medicinal ingredients are** below)

MARCAINE (multidose vials) should not be used in patients who are allergic to methylparaben, other parabens or PABA.

MARCAINE E should not be used in patients who are allergic to:

- sodium metabisulfite

Because of the potential for irreversible joint damage, pain following joint surgery should not be managed by infusing MARCAINE, MARCAINE SPINAL and MARCAINE E into the joint (i.e. by use of a post-operative "pain pump").

What the medicinal ingredients are:

Bupivacaine hydrochloride.

Bupivacaine hydrochloride with epinephrine.

What the non-medicinal ingredients are:

MARCAINE contains sodium chloride, sodium hydroxide and/or hydrochloric acid and water for injection. Multidose vials contain methylparaben as a preservative.

MARCAINE E contains sodium chloride, sodium hydroxide and/or hydrochloric acid, monothioglycerol, ascorbic acid, sodium lactate 60% solution, edetate calcium disodium, sodium metabisulfite and water for injection.

MARCAINE SPINAL contains dextrose, sodium hydroxide and/or hydrochloric acid and water for injection.

What dosage forms it comes in:

MARCAINE is available as 0.25% (2.5 mg/mL), 0.5% (5 mg/mL) and 0.75% (7.5 mg/mL) in single-dose glass vials of 10 and 20 mL as well as multidose vials of 50 mL.

MARCAINE E is available in single-dose glass vials as 0.25% (2.5 mg/mL) and 0.5% (5 mg/mL) with epinephrine (as bitartrate) (1:200,000).

MARCAINE SPINAL is available in single-dose glass vials as 0.75% (7.5 mg/mL).

WARNINGS AND PRECAUTIONS

You should talk to your doctor prior to surgery:

- about health problems you have now or have had in the past;
- about other medicines you take, including ones you can buy without prescription;
- if you are taking other medicines such as drugs used to treat irregular heart activity (anti-arrhythmics);
- if you have ever had a bad, unusual allergic reaction to bupivacaine or any other medicines ending with "-caine";
- if you are allergic to methylparaben, other parabens or PABA;
- if you think you may be allergic or sensitive to any ingredients in MARCAINE, MARCAINE E or MARCAINE SPINAL (see above). Sodium metabisulphite might cause allergic reactions (e.g., itching, hives, facial swelling and breathing difficulties) in susceptible people, especially those with a history of asthma or allergy;
- if you have heart, liver or kidney disease;
- if you are pregnant, plan to become pregnant or are breastfeeding;
- if you are planning to drive or operate any tools or machinery on the day of surgery, because MARCAINE, MARCAINE E and MARCAINE SPINAL may temporarily interfere with your reactions and muscular coordination.

INTERACTIONS WITH THIS MEDICATION

Many drugs interact with MARCAINE, MARCAINE E and MARCAINE SPINAL. Tell your doctor about all prescription, over-the-counter and natural health products that you are using (See WARNINGS AND PRECAUTIONS above).

Usage of such medicines at the same time as MARCAINE, MARCAINE E or MARCAINE SPINAL may increase the risk of serious side effects.

PROPER USE OF THIS MEDICATION

Usual dose:

MARCAINE, MARCAINE E and MARCAINE SPINAL should be administered by a doctor. The dose given is decided by the doctor based on the clinical need and your physical condition.

Overdose:

Serious adverse effects resulting from an overdose are extremely rare and need special treatment. The doctor is trained and equipped to handle such situations.

The first signs that too much MARCAINE, MARCAINE E or MARCAINE SPINAL has been given usually take the form of lightheadedness, numbness of the lips and round the mouth, numbness of the tongue, hearing disturbances, tingling in the ears, and visual disturbances. Tell your doctor immediately if you notice any of these symptoms. Speech symptoms, muscular twitching or tremors are more serious.

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

If the administration of MARCAINE, MARCAINE E and MARCAINE SPINAL is stopped as soon as early signs of overdose appear, the risk of serious adverse effects rapidly decreases.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like any medication, MARCAINE, MARCAINE E and MARCAINE SPINAL may cause side effects in some people.

Medicines affect different people in different ways. Just because side effects have occurred in some patients, does not mean that you will get them.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Sudden life-threatening allergic reactions (such as anaphylaxis) are rare, affecting less than 1 in 1,000 people. Possible symptoms include sudden onset of rash, itching or lumpy rash (hives); swelling of the face, lips, tongue or other parts of the body; and shortness of breath, wheezing or difficulty breathing. **If you think**

that MARCAINE, MARCAINE E or MARCAINE SPINAL is causing an allergic reaction, tell your doctor immediately.

There are other possible side effects that have been reported for MARCAINE, MARCAINE E and MARCAINE SPINAL. Tell your doctor or anesthesia professional if you experience any of the following side effects:

Frequency	Symptom/ Effect
Very Common	Low blood pressure (hypotension). This might make you feel dizzy or light-headed.
	Feeling sick (nausea).
Common	Pins and needles.
	Feeling dizzy.
	Headache.
	Slow or fast heart beat (bradycardia, tachycardia).
	High blood pressure (hypertension).
	Being sick (vomiting).
	Difficulty in passing urine.
	High temperature (fever) or stiffness (rigor).
Uncommon	Back pain.
	Anxiety.
	Decreased sensitivity or feeling in the skin.
	Fainting.
	Difficulty breathing.
Rare	Low body temperature (hypothermia).
	Some symptoms can happen if the injection was given into a blood vessel by mistake, or if you have been given too much MARCAINE, MARCAINE E or MARCAINE SPINAL (see also "OVERDOSE" section above). These include fits (seizures), feeling dizzy or light-headed, numbness of the lips and around the mouth, numbness of the tongue, hearing problems, problems with your sight (vision), problems with your speech, stiff muscles, and trembling.
Rare	Heart attack (cardiac arrest).
	Uneven heart beat (arrhythmias).

Other possible side effects include:

Numbness, due to nerve irritation caused by the needle or the injection. This does not usually last for long.

Possible side effects seen with other local anesthetics which might also be caused by MARCAINE, MARCAINE E or MARCAINE SPINAL include:

Damaged nerves. Rarely (affecting less than 1 in 1,000 people), this may cause permanent problems.

If too much MARCAINE, MARCAINE E or MARCAINE SPINAL is given into the spinal fluid, the whole body may become numbed (anesthetised).

This is not a complete list of side effects. For any unexpected effects while taking MARCAINE, MARCAINE SPINAL or MARCAINE E, contact your doctor or pharmacist.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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.

MORE INFORMATION

NOTE: This CONSUMER INFORMATION leaflet provides you with the most current information at the time of printing.

This document plus the full product monograph, prepared for health professionals can be found by contacting the sponsor, Pfizer Canada ULC, at: 1-800-463-6001.

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