

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

#### MARCAINE®

##### (Bupivacaine Hydrochloride Injection)

#### MARCAINE® SPINAL

##### (Bupivacaine Hydrochloride in Dextrose Injection)

#### MARCAINE® E

##### (Bupivacaine Hydrochloride and Epinephrine Injection)

Read this carefully before you start taking **Marcaine, Marcaine Spinal, or Marcaine E** 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 **Marcaine, Marcaine Spinal, or Marcaine E**.

#### Serious Warnings and Precautions

Marcaine, Marcaine Spinal, and Marcaine E are for healthcare professional use only.

Your healthcare professional will be trained in the management and care of local anesthetics, such as Marcaine, Marcaine Spinal, and Marcaine E. They will prepare and give you Marcaine, Marcaine Spinal, and Marcaine E in a hospital setting with the adequate equipment for the proper management of unwanted side effects. They will also monitor your health throughout the treatment.

#### What are MARCAINE, MARCAINE SPINAL, and MARCAINE E used for?

MARCAINE, MARCAINE SPINAL, and MARCAINE E are used in adults and children (2 years of age and older) to prevent or relieve pain to an area of the body. This can include before and after a surgery, during labour, or after a sudden injury.

#### How does MARCAINE, MARCAINE SPINAL, and MARCAINE E work?

MARCAINE, MARCAINE SPINAL, and MARCAINE E belongs to a group of medicines known as local anesthetics. They act by temporarily preventing the nerves around the site of injection from transmitting sensations of pain, heat, or cold. However, you may still experience sensations such as pressure and touch. In this way the nerves are numbed in the part of the body, which will be subjected to surgery.

#### What are the ingredients in MARCAINE, MARCAINE SPINAL, and MARCAINE E?

Medicinal ingredients:

- **MARCAINE:** Bupivacaine hydrochloride.
- **MARCAINE SPINAL:** Bupivacaine hydrochloride.
- **MARCAINE E:** Bupivacaine hydrochloride with epinephrine.

Non-medicinal ingredients:

- **MARCAINE:** hydrochloric acid and/or sodium hydroxide, sodium chloride, and water for injection. Multidose vials also contain methylparaben (as a preservative).
- **MARCAINE SPINAL:** dextrose, hydrochloric acid and/or sodium hydroxide, and water for injection.
- **MARCAINE E:** ascorbic acid, edetate calcium disodium, hydrochloric acid and/or sodium hydroxide, monothioglycerol, sodium chloride, sodium lactate 60% solution, sodium metabisulfite, and water for injection.

**MARCAINE, MARCAINE SPINAL, and MARCAINE E comes in the following dosage forms:**

- **MARCAINE:**
  - Single-dose vials: 0.25% (2.5 mg/mL), 0.5% (5 mg/mL), and 0.75% (7.5 mg/mL) solution.
  - Multidose vials: 0.25% (2.5 mg/mL) and 0.5% (5 mg/mL) solution.
- **MARCAINE SPINAL:**
  - Single-dose vials: 0.75 mg/mL solution.
- **MARCAINE E:**
  - Single-dose vials: 0.25% (2.5 mg/mL) and 0.5% (5 mg/mL) solution.

**Do not use MARCAINE, MARCAINE SPINAL, and MARCAINE E if:**

- you are allergic to bupivacaine, other anesthetics that end with “-caine”, or any of the other ingredients in MARCAINE, MARCAINE SPINAL, and MARCAINE E. If you are unsure ask your healthcare professional.
- you are planning to use MARCAINE, MARCAINE SPINAL, or MARCAINE E for intravenous regional anesthesia (Bier block) that can be used to reduce pain in the arms or legs.
- you are currently receiving or planning to receive anesthetics (medicines used to prevent the feeling of pain during surgeries/operations) during labour.
- you are in severe shock (a blood circulation failure), have a heart block (electrical signal that controls the heart from beating is partially or completely blocked), and have a severe reaction to an infection (sepsis) near the proposed site of injection for the MARCAINE, MARCAINE SPINAL, or MARCAINE E injection.

In addition:

- Do not use MARCAINE SPINAL single dose vials for spinal anesthesia if you have a condition that is not suitable for spinal anesthesia (e.g., shock, untreated high or low blood pressure, and certain stomach or intestine problems).
- Do not use MARCAINE multidose vials that contain methylparaben (as a preservative):
  - for epidural anesthesia (injection into the sac of fluid around your spinal cord called the epidural space);
  - for spinal anesthesia (into the fluid around your spinal cord and brain);
  - intraocularly (into the eye);
  - retroocularly (behind the eye); or
  - if you are allergic to substances known as para-aminobenzoic acid (PABA), methylparaben, other parabens;
- Do not use MARCAINE E if you are allergic to a substance known as sodium metabisulfite.

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

- have heart, blood vessel, or blood circulation problems;
- have kidney problems;
- have liver problems;
- have thyroid gland problems;
- have high blood pressure;
- have inflamed or infected skin tissue;
- have diabetes;
- have a condition that causes weakness or frailty;
- have recently had a surgery or planning to have a surgery;
- are over 65 years of age or under 18 years of age;
- are severely ill;
- are pregnant or are planning to become pregnant;
- are breastfeeding or planning to breastfeed. Bupivacaine can pass into your breast milk.

**Other warnings you should know about:**

**Driving and using machines:** MARCAINE, MARCAINE SPINAL, and MARCAINE E may temporarily interfere with your reactions and coordination. Before you do tasks that may require your attention, you should wait until you know how you react to your treatment.

**Testing and monitoring:** Your healthcare professional will regularly monitor your health throughout your treatment. This may include monitoring:

- how you react to your dose;
- your blood pressure, heart rate, heart rhythm, and heart and blood vessel functions;
- your breathing and lung function;
- your vision.

**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 MARCAINE, MARCAINE SPINAL, and MARCAINE E:**

- anesthetics, medicines used to prevent pain during surgery (e.g., lidocaine, ropivacaine, mepivacaine, chloroprocaine, prilocaine, halothane, cyclopropane, trichloroethylene, and enflurane).
- antiarrhythmics, medicines used to treat abnormal heartbeat and heart rhythms (e.g., procainamide, disopyramide, tocainide, mexiletine, flecainide, and amiodarone).
- antidepressants, medicines used to treat depression (e.g., monoamine oxidase (MAO) inhibitors, triptyline, and imipramine).
- beta-blockers, medicines used to lower blood pressure (e.g., propranolol).
- H<sub>2</sub>-antagonists, medicines used to treat ulcers (e.g., cimetidine and ranitidine).
- medicines containing a substance called ergot.
- neuroleptics, medicines used to treat mental health disorders (e.g., phenothiazines and butyrophenones).
- sedatives, medicines that can increase drowsiness.

- vasoconstrictors, medicines used to treat low blood pressure.

### **How to take MARCAINE, MARCAINE SPINAL, and MARCAINE E:**

Your healthcare professional will prepare and give you MARCAINE, MARCAINE SPINAL, or MARCAINE E in a healthcare setting. The site of injection will be determined by your healthcare professional as follows:

- **MARCAINE:** retrobulbar (behind the eye), epidural (into the space around your spinal cord), or block/infiltration (near a nerve or group of nerves).
- **MARCAINE SPINAL:** intraspinal (into the fluid around your spinal cord and brain).
- **MARCAINE E:** epidural (into the space around your spinal cord), or block/infiltration (near a nerve or group of nerves).

For children (2 to 18 years of age), the route of administration may also be determined by age.

### **Usual dose:**

MARCAINE, MARCAINE SPINAL, and MARCAINE E will be administered by your healthcare professional. This may depend on:

- your age and weight,
- your medical condition,
- how you respond to the treatment,
- if you take other medicines, and/or
- the type of surgery.

The lowest effective dose of MARCAINE, MARCAINE SPINAL, or MARCAINE E will be used.

### **Overdose:**

Your healthcare professional will monitor you for signs and symptoms of an overdose. If an overdose is suspected, your healthcare professional will act accordingly to manage your side effects.

The symptoms of an overdose may include:

- hearing disturbances,
- lightheadedness,
- muscular twitching or tremors,
- numbness of the lips and around the mouth,
- numbness of the tongue,
- seizures
- speech changes,
- tingling in the ears,
- trembling,
- unconsciousness
- visual disturbances

If you notice any of these symptoms, tell your healthcare professional right away.

If you think you, or a person you are caring for, have taken too much MARCAINE, MARCAINE SPINAL, or MARCAINE E, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**What are possible side effects from using MARCAINE, MARCAINE SPINAL, or MARCAINE E?**

These are not all the possible side effects you may have when taking MARCAINE, MARCAINE SPINAL, or MARCAINE E. If you experience any side effects not listed here, tell your healthcare professional.

Side effects of MARCAINE, MARCAINE SPINAL, or MARCAINE E may include:

- anxiety
- chills,
- headache,
- numbness,
- pins and needles,
- restlessness,
- ringing in the ears.

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	
<b>VERY COMMON</b>			
<b>Hypotension</b> (low blood pressure): dizziness, fainting, light-headedness, blurred vision, nausea, vomiting, or fatigue (may occur when you go from lying or sitting to standing up).		✓	
<b>COMMON</b>			
<b>Arrhythmia</b> (abnormal heart rhythms): rapid, slow, or irregular heartbeat.			✓
<b>Hypertension</b> (high blood pressure): shortness of breath, fatigue, dizziness, fainting, chest pain, chest pressure, swelling in your ankles and legs, bluish colour to your lips and skin, racing pulse, or heart palpitations.		✓	
<b>Urinary retention</b> (inability to pass urine or empty the bladder): hard to start the flow of urine, slow urine stream, or unable to completely empty your bladder when urinating.		✓	
<b>UNCOMMON</b>			
<b>Allergic reaction:</b> difficulty swallowing, wheezing, drop in blood pressure, feeling sick to your stomach, vomiting, hives, rash, swelling of the face, lips, tongue or throat,			✓

itching, shortness of breath, difficulty breathing, red skin, fast heart rate, sneezing, nausea, dizziness, or sweating more than normal.			
<b>Nerve problems:</b> back pain, loss or impairment of motor and sensory function, paralysis, decreased sensitivity or feeling in the skin, or other sensory disturbances.			✓
<b>RARE</b>			
<b>Cardiac arrest</b> (heart suddenly stops beating): fatigue, loss of consciousness, dizziness, difficulty breathing, nausea, chest pain, or heart palpitations.			✓
<b>UNKNOWN FREQUENCY</b>			
<b>Liver problems:</b> yellowing of the skin and eyes (jaundice), dark urine, bleeding easily, swollen <b>stomach</b> , mental disorientation, confusion, sleepiness, <b>coma</b> , fatigue, loss of appetite, itching, stomach pain, nausea, or rash.			✓

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.

#### Reporting 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 healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

#### Storage:

Your healthcare professional will store MARCAINE, MARCAINE SPINAL, and MARCAINE E at 20°C to 25°C. Do not freeze. In addition, MARCAINE E will be protected from light.

Keep out of reach and sight of children.

#### If you want more information about MARCAINE, MARCAINE SPINAL, or MARCAINE E:

- 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.pfizer.ca](http://www.pfizer.ca), or by calling 1-800-463-6001.

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