

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**  
**PATIENT MEDICATION INFORMATION**

**PrXYLOCAINE® Spray**  
**Lidocaine non-aerosol spray**

Read this carefully before you start taking **XYLOCAINE® Spray** 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 **XYLOCAINE® Spray**.

**What is XYLOCAINE® Spray used for?**

XYLOCAINE Spray is used to produce temporary loss of feeling or numbness of the area where it is applied in adults and children, and can be used:

- before certain types of medical procedures are performed by your doctor, e.g., gastrointestinal endoscopy;
- before surgical procedures in the mouth and nose

**XYLOCAINE Spray should be used with caution in children younger than two years of age.**

**How does XYLOCAINE® Spray work?**

XYLOCAINE Spray works on the nerves to create temporary numbness. XYLOCAINE Spray should start to work within 5 minutes after it is applied and its effect should last about 10 to 15 minutes.

**What are the ingredients in XYLOCAINE® Spray?**

Medicinal ingredients: lidocaine 10 mg/metered dose

Non-medicinal ingredients: ethanol, polyethylene glycol 400, essence of banana, menthol, saccharin and purified water.

**XYLOCAINE® Spray comes in the following dosage forms:**

XYLOCAINE Spray is a spray solution that delivers 10 mg per metered dose.

**Do not use XYLOCAINE® Spray if:**

- you are allergic to any local anesthetics of the amide type
- you are allergic to lidocaine, or to any of the other ingredients in the product

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

- have health problems now or have had in the past
- have sepsis, or a skin infection, skin rash, cut, or wound at or near the area you want to apply XYLOCAINE Spray
- have heart, kidney, or liver disease
- have epilepsy (there is a very low risk if used as per PROPER USE OF THE MEDICATION)
- have been diagnosed with porphyria
- are experiencing severe shock
- are pregnant, plan to become pregnant, or are breastfeeding

**Other Warnings you should know about:**

XYLOCAINE Spray may affect your ability to drive. Use caution when driving a vehicle, or dangerous machinery.

**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 XYLOCAINE® Spray:**

- Other local anesthetics
- Mexiletine, amiodarone, propranolol and other drugs used for heart problems
- Cimetidine, used for gastrointestinal problems
- Fluvoxamine, used for depression
- Erythromycin, an antibiotic drug
- Itraconazole, an antifungal drug

Usage of such medicines at the same time as XYLOCAINE Spray may increase the risk of serious side effects.

**How to take XYLOCAINE® Spray:**

- A healthcare professional will give you XYLOCAINE Spray and will decide your dose.
- If you think the effect of XYLOCAINE Spray is too strong or too weak, talk to your healthcare professional.
- Your mouth or throat will be numb after receiving XYLOCAINE Spray. This may make swallowing more difficult and can cause choking. Your tongue or gums may also be numb and you may bite them accidentally. Avoid chewing gum, eating or drinking until you have regained feeling in your mouth and/or throat.

**Dose adjustments may be required in:**

- elderly patients
- children under 18 years of age
- acutely ill patients
- patients with sepsis

**Usual dose:**

The recommended dose of XYLOCAINE Spray **for adults** is:

- 20-60 mg for nasal procedures. No more than 500 mg for short procedures and no more than 600 mg for longer procedures;
- 20-200 mg for procedures such as gastrointestinal endoscopy. No more than 500 mg for short procedures and no more than 600 mg for longer procedures;

- 50-400 mg for procedures in the upper respiratory tract, above the larynx. No more than 200 mg for short procedures and no more than 400 mg for longer procedures.

For short procedures the drug is given for less than one minute. For longer procedures, the drug is given for more than 5 minutes.

The dose **for children (under 18 years of age)** depends on the child's age, weight and physical condition. Children over 12 years of age considered underweight (less than 25 kg) should be dosed with caution. For children under 12 years of age:

- No more than 3 mg/kg of body weight should be used for procedures in the upper respiratory tract, above the larynx;
- No more than 4-5 mg/kg of body weight should be used for nasal and gastrointestinal procedures;
- In neonates and infants, less concentrated lidocaine solutions are recommended.

### **Overdose:**

Early signs of overdosage are light-headedness, abnormal feeling such as burning or prickling around the mouth, numbness of the tongue, loss of hearing or ringing in the ears. In the event of a serious overdosage, changes in your vision, trembling, seizures or unconsciousness may occur.

If you think you have been given too much XYLOCAINE® Spray, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

### **What are possible side effects from using XYLOCAINE® Spray?**

These are not all the possible side effects you may feel when taking XYLOCAINE® Spray. If you experience any side effects not listed here, contact your healthcare professional.

- A burning or prickling feeling around the mouth after surgery
- Irritation at the application site
- Hot/cold sensations, or numbness
- Brief twitching or tremors
- Light-headedness, dizziness, drowsiness and/or blurred vision
- Feelings of nervousness, apprehension, euphoria or confusion
- Unusual sweating
- Hearing problems or ringing in the ears
- Vomiting

| <b>Serious side effects and what to do about them</b>   |                                      |              |   |
|---|--------------------------------------|--------------|---|
| Symptom / effect  | Talk to your healthcare professional |              | Stop taking drug and get immediate medical help |
|   | Only if severe                       | In all cases |   |
| <b>RARE</b><br><b>Allergic reaction:</b><br>difficulty swallowing or breathing, wheezing; drop in blood pressure; feeling sick to your stomach and throwing up; hives or rash; swelling of the face, lips, tongue or throat |                                      |              | X   |
| <b>Bradycardia</b> (abnormally slow heartbeat): dizziness, light-headedness, fatigue, shortness of breath, chest pains  |                                      | X            |   |
| <b>Arrhythmia</b> (abnormal heart rhythms): rapid, slow or irregular heartbeat  |                                      | X            |   |
| <b>Hypotension</b> (low blood pressure): dizziness, fainting, light-headedness, blurred vision, nausea, vomiting, fatigue (may occur when you go from lying or sitting to standing up)                                      |                                      | X            |   |
| <b>Convulsions:</b> seizure, spasms, shaking or fits  |                                      | X            |   |
| <b>Cardiovascular Collapse:</b><br>chest pain or discomfort, rapid or irregular heartbeat, light-headedness, dizziness, shortness of breath   |                                      | X            |   |
| <b>Respiratory Depression</b> (also known as hypoventilation): slow, shallow or weak breathing; blue lips, fingers, toes; confusion; headaches  |                                      | 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, talk to 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 health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### Storage:

XYLOCAINE Spray will be stored at room temperature (15 – 25 °C) protected from light and freezing.

Keep out of reach and sight of children.

### If you want more information about XYLOCAINE® Spray:

- 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://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer's website: <http://aspenpharma.ca/> or by calling 1-844-330-1213.

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