

XYLOCAINE[®] ENDOTRACHEAL
lidocaine non-aerosol spray

**PART III:
CONSUMER INFORMATION**

This leaflet is part III of a two-part "Prescribing Information" published when XYLOCAINE Endotracheal spray was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about XYLOCAINE Endotracheal spray. Contact your doctor or pharmacist if you have any questions about the drug.

Before using XYLOCAINE Endotracheal spray, read this leaflet carefully.

Please keep this leaflet to refer to until you have used up all your XYLOCAINE Endotracheal spray.

This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

ABOUT THIS MEDICATION

WHAT THE MEDICATION IS USED FOR:

XYLOCAINE Endotracheal 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 examination and instrumentation are performed by your doctor, e.g., bronchial examination;
- before surgical procedures in the throat, mouth and nose.

WHAT IT DOES:

XYLOCAINE Endotracheal is the brand name for a topical anesthetic that contains the drug lidocaine. Topical anesthetics are used to produce a temporary loss of feeling or numbness on the area where they are applied.

XYLOCAINE Endotracheal should start to work within 5 minutes after it is applied and its effect should last about 10 to 15 minutes.

WHEN IT SHOULD NOT BE USED:

Do not use XYLOCAINE Endotracheal spray if you:

- are allergic to lidocaine, any other "-caine" type anesthetics, or any of the non-medicinal ingredients in the product (see **NONMEDICINAL INGREDIENTS** below).

WHAT THE MEDICINAL INGREDIENT IS:

lidocaine 10 mg/metered dose.

NONMEDICINAL INGREDIENTS:

XYLOCAINE Endotracheal spray also contains ethanol, polyethylene glycol 400, essence of banana, menthol, saccharin and purified water.

Tell your doctor if you think you may be sensitive to any of the medicinal or non-medicinal ingredients.

WHAT DOSAGE FORMS IT COMES IN:

XYLOCAINE Endotracheal spray, 50 mL non-aerosol glass spray bottle with a metered dose valve and a single use plastic nozzle.

WARNINGS AND PRECAUTIONS

BEFORE you use XYLOCAINE Endotracheal spray tell your doctor or dentist:

- about all health problems you have now or have had in the past;
- about other medicines you take, including ones you can buy without a 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 or allergic reaction to XYLOCAINE Endotracheal spray or any other medicines ending with "caine";
- if you think you may be allergic or sensitive to any ingredients in XYLOCAINE Endotracheal spray (see above);
- if there is an infection, skin rash, cut or wound at or near the area you want to apply XYLOCAINE Endotracheal;
- if you have a skin condition that is severe or that covers a large area;
- if you have severe heart, kidney or liver disease (see **PROPER USE OF THIS MEDICATION**);
- if you have epilepsy (there is very low risk if used as per **PROPER USE OF THE MEDICATION** section);
- If you or someone in your family has been diagnosed with porphyria;
- if you are experiencing severe shock;
- if you are pregnant, plan to become pregnant or are breastfeeding.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or dentist about any other drugs you take or have recently taken, including:

- drugs you can buy without a prescription;
- anti-arrhythmic drugs for heart problems (e.g. mexiletine, amiodarone) (see **PROPER USE OF THIS MEDICATION**);
- other anesthetics (see **PROPER USE OF THIS MEDICATION**);
- propranolol for heart problems or cimetidine for gastrointestinal problems, if high doses of XYLOCAINE Endotracheal spray will be used for a long time;

- fluvoxamine, for depression, if high doses of XYLOCAINE Endotracheal spray will be used for a long time.

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

PROPER USE OF THIS MEDICATION

USUAL DOSE:

A doctor/dentist/nurse will give you XYLOCAINE Endotracheal spray. The nozzles should not be re-used and should be disposed of immediately after use.

The dose given is decided by the doctor/dentist. If you have the impression that the effect of XYLOCAINE Endotracheal spray is too strong or too weak, talk to your doctor/dentist.

Conditions where dose adjustments may be required:

- elderly patients
- children under 18 years of age
- acutely ill patients
- patients with severe liver disease
- patients with severe kidney disease
- patients also treated with other anesthetics or certain antiarrhythmic drugs (such as amiodarone or mexiletine)

Dose for Adults:

The recommended dose of XYLOCAINE Endotracheal spray 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 respiratory tract procedures. No more than 400 mg for short procedures and no more than 600 mg for longer procedures;
- 50-200 mg for procedures in the upper respiratory tract. 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.

Dose for Children (Under 18 Years of Age):

The dose depends on the child's age, weight and physical condition, however, 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 upper respiratory tract procedures;

- 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:

In case of drug overdose, contact the regional Poison Control Centre, hospital emergency department or a health care practitioner immediately, even if there are no symptoms.

Early signs of overdosage are light-headedness, dizziness and sometimes blurred vision. In the event of a serious overdosage, trembling, seizures or unconsciousness may occur.

If the early signs of overdosage are noticed and no further XYLOCAINE Endotracheal spray is given, the risk of serious side effects occurring rapidly decreases. If you think you or anyone else is experiencing any of the above signs, contact a doctor or go to the nearest hospital right away.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like any medication, XYLOCAINE Endotracheal spray may cause side effects in some people.

Avoid eating or chewing gum when XYLOCAINE Endotracheal is sprayed in the mouth or throat since numbness in these areas may interfere with swallowing and could potentially cause choking. Numbness of the tongue or gums may also increase the danger of injury due to biting.

Avoid exposure to extreme hot or cold temperatures (e.g. food, drink) until complete sensation has returned.

Avoid contact with the eyes because numbness in the eyes may prevent you from noticing if you get something in your eye.

With the recommended doses, XYLOCAINE Endotracheal spray has no effect on the ability to drive and use machines.

Medicines affect different people in different ways. Just because side effects have occurred in some patients, does not mean that you will get them. If any side effects bother you, or if you experience any unusual effects while you are using XYLOCAINE Endotracheal spray, stop using it and check with your doctor or pharmacist as soon as possible.

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

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency help
		Only if severe	In all cases	
Rare	Allergic reaction such as: redness, itching or swelling of your skin, hives, burning, stinging, or any other skin problems, swelling of the neck area, or any difficulty with breathing, not present before using this medicine	X		X

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

XYLOCAINE Endotracheal spray can cause serious side effects if too much is used. These include: drowsiness, numbness of your tongue, light-headedness, ringing in your ears, blurred vision, vomiting, dizziness, unusually slow heart beat, fainting, nervousness, unusual sweating, trembling or seizures.

The above are extremely rare and usually require large amounts of XYLOCAINE Endotracheal spray over a long period of time.

Contact your doctor/dentist or go to the nearest hospital immediately if any of these symptoms appear.

HOW TO STORE IT

Keep XYLOCAINE Endotracheal spray at room temperature. Protect from freezing. Your doctor/dentist or the hospital will normally store XYLOCAINE Endotracheal spray. The staff are responsible for the storing, using and disposing of the solution in the correct way. The nozzles should not be re-used and should be disposed of immediately after use.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701D
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

Important Note: This leaflet alerts you to some of the times you should call your doctor. Other situations which cannot be predicted may arise. Nothing about this leaflet should stop you from calling your doctor with any questions or concerns you have about using XYLOCAINE Endotracheal spray.

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

For the most current information, the Consumer Information Leaflet plus the full Prescribing Information, prepared for health professionals can be found at: www.astrazeneca.ca or by contacting the sponsor, AstraZeneca Canada Inc. at:
Customer Inquiries – 1 (800) 668-6000,
Renseignements – 1 (800) 461-3787.

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Last revised: March 21, 2012