

PART III: CONSUMER INFORMATION

^NULTIVA[®] (Remifentanil Hydrochloride)

This leaflet is part III of a three-part “Product Monograph” published when ^NULTIVA[®] was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ^NULTIVA[®]. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

ULTIVA[®] is a pain medication used before and/ or during surgery.

What it does:

ULTIVA[®] reduces the pain during surgery.

When it should not be used:

ULTIVA[®] should not be used in patients who:

- are allergic to remifentanil
- are pregnant or nursing

What the medicinal ingredient is:

Remifentanil hydrochloride

What the nonmedicinal ingredients are:

Glycine, hydrochloric acid, water for injection.

WARNINGS AND PRECAUTIONS

BEFORE you undergo surgery, tell your doctor or pharmacist if:

- you are pregnant or nursing
- you are allergic to remifentanil

INTERACTIONS WITH THIS MEDICATION

Tell your doctor if you are taking :

- benzodiazepines (Valium, Versed)
- opioids (Morphine, Codeine)

They may interact with ULTIVA[®].

PROPER USE OF THIS MEDICATION

Usual dose:

The proper dose is determined by a doctor trained in the administration of analgesics and general anesthesia.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Common side effects include: respiratory depression, slow heartbeat, low blood pressure, and skeletal muscle rigidity. Your anesthetist knows how to manage them during surgery.

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

You should immediately contact your physician or anesthesia professional if you have any of the following reactions after surgery.

Nausea
 Low blood pressure
 Vomiting
 Muscle tightness
 Slow heartbeat
 Shivering
 Fever
 Dizziness
 Visual disturbance
 Headache
 Respiratory depression
 Transient cessation of respiration
 Itch
 Rapid heartbeat
 Postoperative pain
 High blood pressure
 Agitation
 Hypoxia

This is not a complete list of side effects. For any unexpected effects while taking ULTIVA[®], contact your doctor or pharmacist.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Canada Vigilance:

By toll-free telephone: 866-234-2345

By toll-free fax 866-678-6789

Online: www.healthcanada.gc.ca/medeffect

By email: CanadaVigilance@hc-sc.gc.ca

By regular mail:

Canada Vigilance National Office
Marketed Health Products Safety and
Effectiveness Information Division
Marketed Health Products Directorate
Health Products and Food Branch
Health Canada
Tunney's Pasture, AL 0701C
Ottawa ON K1A 0K9

NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying Canada Vigilance. The Canada Vigilance Program does not provide medical advice

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: <http://www.abbott.ca> or by contacting the sponsor, Abbott Laboratories, Limited, at: 1-800-699-9948.

This leaflet was prepared by Abbott Laboratories, Limited

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