

**Health Canada Endorsed Important Safety Information on
N^oULTIVA® (Remifentanil hydrochloride)**



December 21, 2007

Subject: Recall of N^oULTIVA® (remifentanil hydrochloride) 1 mg vials due to potential for overdose

Dear Health Care Professional,

Abbott Laboratories, Limited (Abbott), in consultation with Health Canada, would like to inform you that a recall has been initiated on certain lots of N^oULTIVA® 1 mg vials due to a printing defect that could potentially lead to a 10-fold overdose of ULTIVA.

- A printing defect identified on a limited number of ULTIVA 1 mg vial labels could result in a 10-fold overdose of ULTIVA if the strength is misinterpreted as 0.1 mg instead of 1 mg.
- The printing defect is limited to the following ULTIVA 1 mg vial lots: 49290DD, 52185DD and 56275DD. The printing defect does not affect the ULTIVA 2 mg vials. Please note that an ULTIVA 0.1 mg vial does not exist.

The printing defect on a limited number of ULTIVA 1 mg vial labels consists of a small area where ink was not transferred onto the label. This defect, the size of a decimal point, appears on certain labels directly before the ULTIVA strength (1 mg) and may be mistaken for 0.1 mg instead of 1 mg.

In the interest of patient safety, Abbott has initiated a recall of ULTIVA 1 mg lots 49290DD, 52185DD and 56275DD to the end-user level. This precautionary measure is being taken to reduce the risk of ULTIVA overdose. To date, Abbott has not received any report of adverse reactions related to this printing defect.

ULTIVA (remifentanil hydrochloride) is indicated for i.v. administration as an analgesic agent for use during the induction and maintenance of general anesthesia for inpatient and outpatient procedures.

According to the Product Monograph, overdosage with ULTIVA (remifentanil hydrochloride), as with all potent opioid analgesics, would be manifested by an extension of the pharmacological actions of the drug. Expected signs and symptoms of overdosage include: apnea, chest-wall rigidity, seizures, hypoxemia, hypotension, and bradycardia. For additional information on treatment of ULTIVA overdose, please refer to the Product Monograph.

Abbott has initiated a recall to the end-user level and is organizing the return of the product in accordance with regulatory requirements for narcotics. Should you have affected vials on hand, please carefully follow the procedure in place in your institution.

Managing marketed health product-related adverse reactions depends on health care professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing adverse reactions are generally presumed to underestimate the risks associated with health product treatments. Any occurrences of serious and/or unexpected adverse reactions or accidental overdose in patients receiving ULTIVA should be reported to Abbott or Health Canada at the following addresses:

Abbott Laboratories, Limited
Medical Information Department
8401 Trans-Canada Highway
Saint-Laurent, Quebec H4S 1Z1
Tel.: 1-800-567-2226, Fax : (514) 832-7824 or Toll Free Fax: (866) 514-7824

Any suspected adverse reaction can also be reported to:

Canada Vigilance Program
Marketed Health Products Directorate
HEALTH CANADA
Address Locator: 0701C
OTTAWA, Ontario, K1A 0K9
Tel: (613) 957-0337 or Fax: (613) 957-0335
Toll Free Tel: (866) 234-2345 or Toll Free Fax: (866) 678-6789
CanadaVigilance@hc-sc.gc.ca

The [AR Reporting Form](#) and the [AR Guidelines](#) can be found on the Health Canada web site or in *The Compendium of Pharmaceuticals and Specialties*.

http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/form/ar-ei_form_e.html
http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/guide/ar-ei_guide-ldir_e.html

Abbott reiterates its commitment to the health and safety of patients and the delivery of quality products.

Should you have any questions or require additional information regarding ULTIVA, please contact the Abbott Medical Information Department at 1-800-361-7852.

Sincerely,

Original signed by

A. Tom Koutsavlis, MD, MSc, CSPQ, FRCPC
Medical Director
Abbott