

Health Canada Endorsed Important Safety Information Update on
Mylan-Nitro Sublingual Spray 0.4 mg per Metered Dose



October 14, 2014

Dear Health Care Professional,

Subject: Update for Mylan-Nitro Sublingual Spray 0.4 mg Per Metered Dose (DIN: 02243588) – Unaffected Product Has Now Become Available

Mylan Pharmaceuticals ULC, in consultation with Health Canada, is providing additional information as a follow-up to the communication sent on September, 22, 2014, regarding the potential of defective pumps in certain lots of Mylan-Nitro Sublingual Spray 0.4 mg/metered dose (DIN: 02243588). Unaffected product has now become available in limited supply and will be shipped to pharmacies and wholesalers.

- Patients who have received the affected product (see table below) should continue to use it following the instructions previously provided, which directs them to use each canister currently in their possession for about 70-75 sprays (a third of its content).
- When each previously dispensed canister from the affected lots has been used for 70-75 sprays, it will require replacement. At the time of prescription refill, patients will be provided with one unaffected product canister available in stock.
- Pharmacists should clearly explain to patients that the product they are now receiving is unaffected, as indicated by the two verification labels affixed (see picture below), and the new canister should be fully used up to the regular rate of 200 prescribed doses.
- For a period of time patients may have in their possession both affected and unaffected canisters. Pharmacists will need to clearly explain the use of each.
- Patients should be reminded to always have a spare spray canister readily available for use in case their current canister runs out of medication or fails to work properly.

This recall is extended to the pharmacy and wholesaler level and applies only to product not yet dispensed. Pharmacists and healthcare professionals are not required to contact patients and advise them to return the product they have received.

The lot numbers of affected product being recalled are:

Lot Number	Expiry date
2L734	Nov-14
2L731	Nov-14
3E830	May-15
3E828	May-15
3F834	June-15
3F837	June-15
3K873	Oct-16
3K877B	Oct-16
4B948	Feb-17
4B949	Feb-17
4D973	Apr-17

Distribution of affected product lots should be stopped and existing stock returned to Mylan only once unaffected product is received. In order to clearly identify unaffected product,

each unit of unaffected product will have two verification labels: one affixed to the top of the canister closure, and one on a side of the canister carton, respectively, as depicted in the picture below.



Product released by Mylan for distribution within the next twelve months will continue to be marked with verification labels, in order to address any potential confusion between previously distributed affected product, which may be with patients, and new unaffected product lots.

Mylan Pharmaceuticals ULC has continued to diligently work on resolving this issue as quickly as possible and resuming regular product supply.

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 case of serious adverse reactions, or unexpected adverse reactions in patients receiving Mylan-Nitro Sublingual Spray 0.4 mg per metered dose should be reported to Mylan Pharmaceuticals ULC or Health Canada.

Mylan Pharmaceuticals ULC
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M8Z 2S6

Mylan ULC Customer Relations

Phone: 1-800-575-1379

Fax: 1-855-236-2990

E-mail: customerservice@mylan.ca

To correct your mailing address or fax number, contact Mylan Pharmaceuticals ULC

You can report any suspected adverse reactions associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect Canada's Web page on [Adverse Reaction Reporting](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax

For other health product inquiries related to this communication, contact Health Canada at:
Health Products and Food Branch Inspectorate

E-mail: DCVIU_UVCEM@hc-sc.gc.ca

Telephone: 1-800-267-9675

Fax: 613-946-5636

Sincerely,

Original signed by

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Mylan Pharmaceuticals ULC