

Information Update - Mylan-Valsartan medications voluntarily recalled as a precaution due to an impurity

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 (<http://www.healthycanadians.gc.ca/report-signalez/index-eng.php>)

Starting date: November 28, 2018
Type of communication: Information Update
Subcategory: Drugs
Source of recall: Health Canada
Issue: Important Safety Information
Audience: General Public
Identification number: RA-68448

- [What you should do](#)
- [Media enquiries](#)
- [Public enquiries](#)

Issue:

Mylan Pharmaceuticals ULC is voluntarily recalling four lots of Mylan-Valsartan tablets (40 mg, 80 mg, 160 mg and 320 mg strength) after testing found low levels of an impurity, N-nitrosodiethylamine (NDEA).

Valsartan is a drug used to treat patients with high blood pressure to help prevent heart attacks and stroke. It is also used in patients who have had heart failure or a recent heart attack.

The products are being recalled as a precautionary measure. While the levels of NDEA found in the active pharmaceutical ingredient (valsartan), which is manufactured by Mylan Laboratories Limited in India, are low, they are above what is considered reasonably safe if the drug were taken over a lifetime. Given the length of time that the affected products have been on the Canadian market, this recall is being taken with an abundance of caution.

This latest recall is further to recent recalls and other actions taken in Canada and internationally as a result of NDEA and another impurity, N-nitrosodimethylamine (NDMA), being found in certain drugs (see links below for related communications). Both NDEA and NDMA are classified as probable human carcinogens, which means that long-term exposure could increase the risk of cancer.

Health Canada continues to work with companies and international regulatory partners to determine the scope and root cause of the issue, and to confirm that the necessary actions are taken to address it and prevent it from re-occurring. The Department will monitor these recalls. Should additional safety concerns be identified, Health Canada will take appropriate action and continue to inform Canadians.

Shortages are not anticipated as a result of this recall as there are alternative products available on the Canadian market. As with previous communications regarding NDEA and NDMA, Health Canada is advising that there is no immediate risk to patients taking these medications, since the risk of cancer is with long-term exposure to these impurities. Patients should not stop taking their medication unless on the advice of their healthcare provider.

Affected products

The following Mylan valsartan products are being recalled.

(Note: a related list of other valsartan products that have and have NOT been recalled is available in this previous notice

(<http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2018/67552a-eng.php>.)

Product name/Active Pharmaceutical Ingredient	Strength	DIN	Lot

MYLAN-Valsartan	40 mg	02383527 (https://health-products.canada.ca/dpd-bdpp/info.do?lang=en&code=86928)	3048813-1
MYLAN-Valsartan	80 mg	02383535 (https://health-products.canada.ca/dpd-bdpp/info.do?lang=en&code=86929)	3056368
MYLAN-Valsartan	160 mg	02383543 (https://health-products.canada.ca/dpd-bdpp/info.do?lang=en&code=86930)	3056371
MYLAN-Valsartan	320 mg	02383551 (https://health-products.canada.ca/dpd-bdpp/info.do?lang=en&code=86931)	3048815-1

What you should do

- Continue taking your valsartan medication **unless** you have been advised to stop by your health care provider.
- Contact your health care provider to discuss treatment options if you have been using an affected product.
- Ask your pharmacist if you are unsure whether you are taking a recalled product.
- Contact your health care provider if you have taken a recalled product and you have concerns about your health.
- Contact Mylan by telephone at 1-800-575-1379 or email at recall@mylan.ca (<mailto:recall@mylan.ca>) if you have questions about the recall.
- Report any health product-related side effects (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) or complaints (<http://healthycanadians.gc.ca/apps/radar/MD-IM-0005.08.html>) to Health Canada.

Media enquiries

Health Canada
613-957-2983

Public enquiries

613-957-2991
1-866-225-0709

For more information

- Health Canada information update (2018-10-02): Health Canada finds Zhejiang Huahai Pharmaceuticals site non-compliant with requirements for the manufacture of drug ingredients (<http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2018/67870a-eng.php>)
- Health Canada information update (2018-09-13): Health Canada advises of a second impurity linked to recalled valsartan drugs (<http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2018/67746a-eng.php>)
- Health Canada information update (2018-09-10): Valsartan NDMA Health Risk Assessment (<https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2018/67734a-eng.php>)
- Health Canada information update (2018-08-18): Teva Canada expands recall of valsartan drugs to include additional lots, as a precaution (http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2018/67552a-eng.php?_ga=2.186111849.1130786600.1536540324-1989020253.1520525748)
- Health Canada advisory (2018-07-09): Several drugs containing valsartan being recalled due to contamination with a potential carcinogen (<http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2018/67202a-eng.php>)

Stay connected (<https://www.canada.ca/en/services/health/stay-connected.html>) with Health Canada and receive the latest advisories and product recalls.

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