Drug News
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Issue Number 198

This is a monthly digest of local and overseas drug safety news released by the Drug Office of the Department of Health in April 2026 with relevant information update before publish. For the latest news and information, please refer to public announcements or the website of the Drug Office of the Department of Health (http://www.drugoffice.gov.hk).

Safety Update

European Union: Ontozry (cenobamate): New Requirements for Liver Monitoring Due to Reports of Severe Liver Injury

On 10 April 2026, the European Medicines Agency (EMA) announced that its Pharmacovigilance Risk Assessment Committee (PRAC) agreed on a direct healthcare professional communication to inform healthcare professionals that cases of severe liver injury with hepatic failure have been reported in patients treated with the medicine Ontozry. Most cases occurred when the medicine was used alongside other anti-seizure medications.

Prescribers are recommended to conduct liver function tests before starting treatment with Ontozry and throughout treatment.

They should carry out a prompt clinical evaluation and liver function tests in patients who have symptoms indicating liver injury, such as fatigue, anorexia, right upper abdominal discomfort, dark urine, or jaundice.

Patients should be advised to immediately seek medical attention if they experience signs or symptoms suggesting liver injury.

If liver injury is suspected or detected, dose reduction or discontinuation of Ontozry should be considered, in line with the guidelines of the summary of product characteristics (i.e., unless required, avoid abrupt discontinuation to minimise the risk of rebound seizures).

Increased liver enzyme levels are already listed in Ontozry's product information as a common side effect (which may occur in up to 1 in 10 people).

Following its review of the cases, PRAC recommended adding liver injury as a rare side effect (which may occur in up to 1 in 1,000 people) to Ontozry's product information and including warnings for patients and healthcare professionals.

Ontozry is a medicine for treating epileptic seizures starting in one specific part of the brain (focal seizures), including those that eventually spread to the whole brain (secondary generalisation). It is used as an add-on to other epilepsy medicines for adults with seizures that are not controlled despite having tried at least two other treatments.

In Hong Kong, there are 9 registered pharmaceutical products containing cenobamate. All products are prescription-only medicines. As of the end of April 2026, the Department of Health (DH) had not received any case of adverse drug reaction with regard to cenobamate. In light of the above EMA's announcement, the DH issued letters to inform local healthcare professionals to draw their attention on 13 April 2026, and the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board of Hong Kong

Canada: Health Professional Risk Communication: ALECENSARO (alectinib) and the Risk of Severe Hypertriglyceridemia

On 22 April 2026, Health Canada issued the following announcement:

Affected products
ALECENSARO, alectinib capsules, 150 mg

Issue
Hypertriglyceridemia, including severe and life-threatening events, has been identified as an adverse reaction associated with ALECENSARO. Severe hypertriglyceridemia is considered a medical emergency, as it may lead to acute pancreatitis.

Audience

Healthcare professionals involved in the treatment of lung cancer, including medical oncologists, thoracic surgeons, surgical oncologists (Quebec), respirologists, oncology nurses, and oncology pharmacists.

Key messages

- Hypertriglyceridemia, including severe and life-threatening events, has been identified as an adverse reaction associated with ALECENSARO (alectinib).
- Severe hypertriglyceridemia is considered a medical emergency, as it may lead to acute pancreatitis.
- Healthcare professionals are advised that:
  - Patients should be counselled on the risks and benefits of ALECENSARO, including the risk of hypertriglyceridemia.
  - Blood triglyceride levels should be measured at baseline before initiating ALECENSARO and periodically during treatment.
  - Patients should be monitored for signs and symptoms of acute pancreatitis, especially those at increased risk.
  - If an acute episode of pancreatitis occurs, ALECENSARO should be temporarily withheld until full recovery before resuming treatment. ALECENSARO should also be temporarily withheld in patients who develop severe or life-threatening hypertriglyceridemia until triglyceride levels recover to moderate levels (see the Information to healthcare professionals section).
- The Canadian Product Monograph for ALECENSARO will be updated to include this safety information.

Background information

ALECENSARO is indicated:

- for the first-line treatment of patients with anaplastic lymphoma kinase (ALK)-positive, locally advanced (not amenable to curative therapy) or metastatic non-small cell lung cancer (NSCLC).
- as monotherapy for the treatment of patients with ALK-positive, locally advanced (not amenable to curative therapy) or metastatic NSCLC who have progressed on or are intolerant to crizotinib.
- for adjuvant treatment following tumour resection for patients with stage IB (tumours ≥ 4 cm) to IIIA* ALK-positive NSCLC.

*According to the American Joint Committee on Cancer [7th edition].

Cumulative data from clinical studies and post-marketing sources identified hypertriglyceridemia as a risk associated with ALECENSARO.

Hypertriglyceridemia adverse events of any grade were reported in 4.3% of patients from pivotal clinical trials, and severe or life-threatening hypertriglyceridemia adverse events were reported in 1.5% of patients from these trials. The onset of severe or life-threatening hypertriglyceridemia adverse events ranged from 106 to 1001 days.

Triglycerides were not consistently monitored in clinical trials. In 3 clinical trials in which triglycerides were measured, laboratory data showed increases from baseline, where the majority of shifts from baseline were from normal to grade 1 (150 mg/dL to 300 mg/dL; 1.71 mmol/L to 3.42 mmol/L); however, grade ≥3 laboratory elevations were also reported in these trials. Overall, observed cases of hypertriglyceridemia were mostly mild to moderate in severity.

In the post-marketing setting, five medically confirmed severe to life-threatening cases of hypertriglyceridemia were reported internationally in patients treated with ALECENSARO. Three of these cases resulted in life-threatening pancreatitis, with all patients ultimately recovering following treatment. One of these cases demonstrated a positive rechallenge for life-threatening hypertriglyceridemia upon ALECENSARO resumption. The onset of these serious cases ranged from 6 weeks to 1 year after the start of ALECENSARO treatment.

Information for consumers

ALECENSARO (alectinib) is a prescription medicine used to treat non-small cell lung cancer in adults.

ALECENSARO can cause high levels of triglycerides (a type of fat) in the blood. In some cases, very high triglyceride levels can be life-threatening and may lead to acute pancreatitis (sudden inflammation of the pancreas), which is a medical emergency.

Healthcare professionals should test their patients' blood triglyceride levels before and during

treatment with ALECENSARO. Patients should be monitored for signs of pancreatitis.

Patients should stop taking ALECENSARO and seek immediate medical attention if they experience symptoms of pancreatitis, such as sudden, severe abdominal pain accompanied by nausea, vomiting, fast heart rate, fast breathing and/or fever.

Patients should talk to their healthcare professional if they have any questions or concerns about this information.

Information for healthcare professionals
Healthcare professionals are advised that:
- Patients should be counselled on the risks and benefits of ALECENSARO, including the risk of hypertriglyceridemia.
- Blood triglyceride levels should be measured at baseline before initiating ALECENSARO and periodically during treatment.
- Patients should be monitored for signs and symptoms of acute pancreatitis, particularly those at increased risk for pancreatitis.
- If an acute episode of pancreatitis occurs, ALECENSARO should be temporarily withheld until full recovery before resuming treatment. ALECENSARO should also be temporarily withheld in patients who develop severe hypertriglyceridemia (blood triglycerides >500 to 1000 mg/dL or >5.7 to 11.4 mmol/L) or life-threatening hypertriglyceridemia (blood triglycerides >1000 mg/dL or >11.4 mmol/L) until triglyceride levels recover to ≤500 mg/dL or ≤5.7 mmol/L. In these patients, risk factors for pancreatitis should be evaluated, and modifiable risk factors should be addressed before resuming treatment with ALECENSARO. ALECENSARO may be resumed at the same dose, with regular triglyceride monitoring.

Action taken by Health Canada
Health Canada, in collaboration with Hoffmann-La Roche Limited, will update the Canadian Product Monograph for ALECENSARO to include this new safety information.

In Hong Kong, Alecensa Capsules 150mg (HK-64854) is an alectinib-containing pharmaceutical product registered by Roche Hong Kong Limited and is a prescription-only medicine. As of the end of April 2026, the Department of Health (DH) had received 27 cases of adverse drug reaction report with regard to alectinib, but these cases were not related to hypertriglyceridaemia and acute pancreatitis. Related news was previously issued by the Singapore Health Sciences Authority, and was reported in the Drug News Issue No. 195. The DH issued letters to inform local healthcare professionals to draw their attention on 19 January 2026. In light of the above Health Canada's announcement, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board of Hong Kong.

Canada: Summary Safety Review: Glucagon-like Peptide 1 Receptor Agonists (GLP-1 RAs) (dulaglutide, liraglutide, lixisenatide, semaglutide and tirzepatide): Assessing the Potential Increased Risk of Pulmonary Aspiration in Patients Undergoing Procedures Requiring General Anesthesia or Deep Sedation

On 30 April 2026, Health Canada issued the following announcement:

Product
Glucagon-like peptide 1 receptor agonists (GLP-1 RAs) (dulaglutide-, liraglutide-, lixisenatide-, semaglutide- and tirzepatide-containing products)

Potential Safety Issue
Pulmonary aspiration (unintentional inhalation of stomach contents, such as food or liquid, into the trachea or lungs) in patients undergoing procedures requiring general anesthesia or deep sedation

Key Messages
- Health Canada's review found a possible link between the use of GLP-1 RAs and the increased risk of pulmonary aspiration in patients undergoing procedures requiring general anesthesia or deep sedation.
- The product safety information in the Canadian product monograph (CPM) for all GLP-1 RAs has been updated to include the increased risk of pulmonary aspiration in patients undergoing procedures requiring general anesthesia or deep sedation.

Overview
It is known that GLP-1 RAs delay gastric emptying (slow the rate at which the stomach releases food into the small intestine). Retained gastric contents are a risk factor for pulmonary aspiration in the context of general anesthesia or deep sedation. Although there is often overlap, pulmonary

consequences of aspiration can be divided into 3 clinical syndromes: mechanical obstruction (physical blockage), chemical pneumonitis (inflammation of the lower lungs directly caused by the inhaled substance), and bacterial aspiration pneumonia (bacterial infection caused by inhaling a substance with a high level of bacteria).

Health Canada reviewed the potential increased risk of pulmonary aspiration in patients taking GLP-1 RAs and undergoing procedures requiring general anesthesia or deep sedation. The safety review was triggered by the publication of communications by the Canadian Anesthesiologists' Society and the American Society of Anesthesiologists aimed at raising awareness of the increased risk of pulmonary aspiration during surgical procedures in patients taking GLP-1 RAs. To ensure safe anesthesia and sedation, these communications highlighted the importance of recognizing that, despite complying with preoperative fasting guidelines (instructions for patients to not consume any food or liquids for a specific duration before surgery), patients treated with GLP-1 RAs are at an increased risk of retained gastric (stomach) content.

Use in Canada

Glucagon-like peptide 1 receptor agonists are a class of prescription drugs authorized for sale in Canada:

- for the medical management of adults with type 2 diabetes (Ozempic/Rybelsus [semaglutide], Plosbrio [semaglutide], Victoza [liraglutide], Trulicity [dulaglutide], Xultophy [insulin degludec and liraglutide], Mounjaro [tirzepatide] and Soliqua [insulin glargine and lixisenatide])
- for chronic weight management in adults and adolescents with obesity or who are overweight (Wegovy [semaglutide], Poviztra [semaglutide], Saxenda [liraglutide] and Zepbound [tirzepatide])
- to treat metabolic dysfunction-associated steatohepatitis (MASH) (a severe form of metabolic-associated fatty liver disease that develops when fat buildup in the liver causes inflammation and scarring) in adults with moderate to advanced liver scarring (fibrosis), but not with cirrhosis (a type of liver disease) (Wegovy)
- to prevent the worsening of kidney disease and death from cardiovascular (having to do with the heart and blood vessels) disease in adults who have both chronic kidney disease and type 2 diabetes (Ozempic)
- to reduce the risk of certain serious cardiovascular events in adults with type 2 diabetes and established cardiovascular disease and/or chronic kidney disease as an add-on to other standard treatments (Ozempic)
- to reduce the risk of non-fatal heart attacks in adults with established heart disease and a body mass index (BMI) equal to or greater than 27 kg/m2 (Wegovy and Poviztra)
- to reduce the risk of death from cardiovascular disease in adults with type 2 diabetes and established cardiovascular disease (Rybelsus and Victoza as an add-on to other standard treatments)
- to reduce the risk of non-fatal stroke in adults with type 2 diabetes and risk factors for heart disease, or established cardiovascular disease (Trulicity)

Glucagon-like peptide 1 receptor agonists have been marketed in Canada since 2010. All GLP-1 RA products are available as subcutaneous (under the skin) injections. Semaglutide is also available as an oral tablet.

Approximately 8.8 million prescriptions for GLP-1 RAs were dispensed by Canadian retail pharmacies in 2024.

Safety Review Findings

- Health Canada reviewed the available information from searches of the Canada Vigilance database and the scientific literature.
- Health Canada reviewed 21 cases (1 Canadian and 20 international) of pulmonary aspiration in patients undergoing general anesthesia or deep sedation, including 5 unique cases from the published literature. Of the 21 cases, 3 (international) were found to be probably linked to the use of GLP-1 RAs, 3 (1 Canadian and 2 international) were possibly linked and 1 (international) was unlikely to be linked. The remaining 14 cases were unassessable due to missing clinical information.
- Health Canada also reviewed real-world data from published sources, which support a link between GLP-1 RAs and retained gastric contents, a known risk factor for pulmonary aspiration during general anesthesia or deep sedation, and an increased number of procedures that could not be completed.

Conclusions and Actions

- Health Canada's review found a possible link between the use of GLP-1 RAs and the increased risk of pulmonary aspiration in patients undergoing general anesthesia or deep sedation.
- The product safety information in the CPM for all GLP-1 RAs has been updated to include this increased risk of pulmonary aspiration in patients undergoing procedures requiring general anesthesia or deep sedation.
- Since the completion of Health Canada's review, other products in the GLP-1 RA drug class (Plosbrio and Poviztra) were authorized. Health Canada is working with the manufacturers of these products to update their respective CPMs.
- Healthcare professionals are encouraged to consider the increased risk of residual gastric content due to delayed gastric emptying, along with possible mitigation strategies, prior to performing surgeries or procedures with general anesthesia or deep sedation.
- Health Canada will continue to monitor safety information involving GLP-1 RAs, as it does for all health products on the Canadian market, to identify and assess potential harms. Health Canada will take appropriate and timely action should new health risks be identified.

In Hong Kong, there are registered pharmaceutical products containing dulaglutide (4 products), liraglutide (5 products), lixisenatide (2 products), semaglutide (11 products), and tirzepatide (6 products). All products are prescription-only medicines. As of the end of April 2026, the Department of Health (DH) had received 11 cases of adverse drug reaction reports with regard to semaglutide, of which 4 cases were related to pulmonary aspiration. The DH had also received adverse drug reaction reports with regard to dulaglutide (5 cases), liraglutide (1 case) and lixisenatide (1 case), but these cases were not related to aspiration or pulmonary aspiration. The DH had not received any case of adverse drug reaction with regard to tirzepatide.

Related news was previously issued by the European Medicines Agency, the United Kingdom Medicines Healthcare Products Regulatory Agency and the Australia Therapeutic Goods Administration, and was reported in Drug News Issues No. 177, 183, and 188. The DH issued letters to inform local healthcare professionals to draw their attention on 15 July 2024. In June 2025, the Registration Committee of the Pharmacy and Poisons Board of Hong Kong discussed the matter, and decided that the sales pack labels and/or package inserts of registered pharmaceutical products containing GLP-1 receptor agonists should contain the relevant safety information about the risk of aspiration and pulmonary aspiration during general anaesthesia or deep sedation. The DH will continue to remain vigilant on any safety update of the drugs issued by other drug regulatory authorities.

Canada: Summary Safety Review: Vitamin B6 Health Products: Assessing the Potential Risk of Peripheral Neuropathy

On 30 April 2026, Health Canada issued the following announcement:

Product

Vitamin B6-containing heath products (natural health products [NHPs] and prescription drugs), with a daily dose of 10 mg vitamin B6 or higher

Potential Safety Issue

Peripheral neuropathy (damage to or disease affecting peripheral nerves)

Key Messages

- Health Canada's review found a possible link between vitamin B6-containing NHPs and the risk of peripheral neuropathy, when taken at daily doses of 10 mg vitamin B6 or higher.
- Health Canada's review did not find sufficient evidence to establish a link between vitamin B6-containing prescription drugs and the risk of peripheral neuropathy, despite these products containing similar amounts of vitamin B6 to what is found in NHPs.
- Health Canada will update the monograph for vitamin B6-containing NHPs to include the risk of peripheral neuropathy. Health Canada expects license holders to update the risk information on product labels for all licensed vitamin B6-containing NHPs with a daily dose of 10 mg vitamin B6 or higher to:
  - include information about the warning signs and symptoms of peripheral neuropathy, including sensory nerve problems (numbness, tingling and pain in the extremities), and
  - advise consumers to stop using these NHPs and consult a healthcare professional if these symptoms occur.

- Health Canada does not recommend an update to the product safety information in the Canadian product monograph (CPM) for vitamin B6-containing prescription drugs at this time, as standardized prescription practices and monitoring of pregnant patients by healthcare professionals are already in place.
- Health Canada will also inform healthcare professionals and consumers about these updates through a Health Product InfoWatch communication and a social media campaign.

Overview

Vitamin B6, also known as pyridoxine, pyridoxamine, pyridoxal and their phosphate derivatives (chemical compounds derived from phosphoric acid), is naturally found in many foods, added to others (supplemented foods and fortified foods), and available as a health product (NHPs and prescription drugs).

When consumed in high amounts (250 mg vitamin B6/day and above), vitamin B6-containing health products may cause peripheral neuropathy. In recent years, however, evidence has suggested that peripheral neuropathy may also be associated with lower doses, which are within the dose range of vitamin B6-containing health products (NHPs and prescription drugs) currently marketed in Canada.

In 2024, Health Canada reviewed this potential risk with the use of vitamin B6-containing NHPs. This safety review was triggered by a scientific study reporting international cases of peripheral neuropathy associated with the use of vitamin B6 health products for daily doses under 100 mg, and after reviewing assessments completed by foreign regulatory agencies (Australia's Therapeutic Goods Administration [TGA], Netherlands Pharmacovigilance Centre Lareb and the European Food Safety Authority [EFSA]).

In 2025, Health Canada also reviewed the potential risk of peripheral neuropathy with the use of vitamin B6-containing prescription drugs to determine if additional risk mitigation measures were needed for these types of products.

Supplemented foods, including caffeinated energy drinks, were not included as part of these reviews and the use of vitamin B6 in these foods is reviewed separately. However, consumers should note that these products may also contain higher amounts of added vitamin B6, similar to NHPs.

Vitamin B6 that is naturally found in whole foods, and vitamin B6 in fortified foods such as breakfast cereals, have not been identified as a safety concern and were not included as part of these reviews.

Use in Canada

- Vitamin B6 is authorized in Canada for use in NHPs, typically to help in energy metabolism and tissue formation, form red blood cells, prevent vitamin B6 deficiency, and maintain/ support the body's ability to metabolize (process) nutrients. Over 4,000 vitamin B6-containing NHPs have been authorized by Health Canada under the Natural Health Products Regulations with recommended daily doses of 10 mg vitamin B6 or higher.
- Prescription drugs that contain vitamin B6 are authorized for sale in Canada for the treatment of nausea and vomiting in pregnancy under the brand name Diclectin (pyridoxine/ doxylamine), or for use as a pregnancy multivitamin under the brand names Pregvit and Pregvit Folic 5. Generic versions are also available. Every year, approximately 230,000 new prescriptions for vitamin B6-containing drugs are filled in Canada.
- Vitamin B6-containing health products have been marketed in Canada for over 20 years.

Safety Review Findings

- Health Canada reviewed the available information provided by foreign regulatory agencies, as well as from searches of the Canada Vigilance database, international databases and the scientific literature.
- At the time of the reviews, Health Canada identified 17 cases (15 Canadian and 2 international) of peripheral neuropathy in patients taking either vitamin B6-containing NHPs (14 cases) or vitamin B6-containing prescription drugs (3 cases). However, 15 of the 17 cases did not meet the criteria for further assessment to determine if there was a link. Though in the 2 remaining cases, which were in patients using vitamin B6-containing NHPs, further assessment was limited due to missing clinical information and the presence of confounders (other factors that may have contributed to the occurrence of peripheral neuropathy), such as the use of other supplements, the potential risk of peripheral neuropathy cannot be excluded.
- Health Canada also reviewed 9 articles published in the scientific literature, which supported a possible link between the use of

vitamin B6-containing health products at daily doses as low as 10 mg vitamin B6 and the risk of peripheral neuropathy. Currently, no well characterized risk factors for developing peripheral neuropathy while using vitamin B6-containing health products have been identified.

- Both foreign regulatory agencies and international pharmacovigilance groups have identified cases of neuropathy with the use of vitamin B6-containing health products and, in some cases, established a possible link between peripheral neuropathy and vitamin B6-containing health products. Among the actions taken in response to their findings are:
  - The TGA's implementation of label updates for vitamin B6-containing health products to include the risk of peripheral neuropathy when the daily dose is over 10 mg of vitamin B6.
  - The EFSA's recommendation to lower the tolerable upper intake level of vitamin B6 to 12 mg/day for foods.

Conclusions and Actions

- Health Canada's review found a possible link between vitamin B6-containing NHPs and the risk of peripheral neuropathy, when the daily dose is 10 mg vitamin B6 or higher.
- Health Canada will update the monograph for vitamin B6-containing NHPs to include the risk of peripheral neuropathy. Health Canada expects license holders to update the risk information on product labels for all licensed vitamin B6-containing NHPs with a daily dose of 10 mg vitamin B6 or higher to:
  - include information about the warning signs and symptoms of peripheral neuropathy, including sensory nerve problems (numbness, tingling and pain in the extremities), and
  - advise consumers to stop using these NHPs and consult a healthcare professional if symptoms occur.
- Health Canada's review did not find sufficient evidence to establish a link between vitamin B6-containing prescription drugs and the risk of peripheral neuropathy despite these products containing similar amounts of vitamin B6 to what is found in NHPs.
- Health Canada does not recommend an update to the product safety information in the CPM for vitamin B6-containing prescription drugs at this time, as standardized prescription practices and monitoring of pregnant patients by healthcare professionals are already in place.
- Health Canada will also inform healthcare professionals and consumers about these updates through a Health Product InfoWatch communication and a social media campaign.
- Health Canada will continue to monitor safety information involving vitamin B6-containing products (NHPs and prescription drugs), as it does for all health products on the Canadian market, to identify and assess potential harms. Health Canada will take appropriate and timely action should new health risks be identified.

In Hong Kong, there are registered pharmaceutical products containing vitamin B6 substance including pyridoxine, while there is no registered pharmaceutical product containing pyridoxal or pyridoxamine. As of the end of April 2026, the DH had received 8 cases of adverse drug reaction reports with regard to pyridoxine, but these cases were not related to peripheral neuropathy.

Related news regarding vitamin B6 and the risk of peripheral neuropathy was previously issued by TGA and Singapore Health Sciences Authority, and was reported in Drug News Issues No. 156, 163, and 196. The DH issued letters to inform local healthcare professionals to draw their attention on 5 October 2022. In December 2024, the Registration Committee of the Pharmacy and Poisons Board of Hong Kong discussed the matter, and decided that the sales pack labels and/or package inserts of registered products containing daily doses over 10mg of vitamin B6 should contain the warning statement related to peripheral neuropathy referenced in the above Health Canada's announcement for vitamin B6-containing NHPs and the TGA's announcement issued on 19 February 2026 "Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible (Contains vitamin B6)". The DH will remain vigilant on any safety update of the drugs issued by other drug regulatory authorities.

Canada: Safety Brief: Falsely Elevated Digoxin Levels with the Chemiluminescent Microparticle Immunoassay Test Method in Patients Receiving Enzalutamide Treatment

On 30 April 2026, Health Canada issued the following announcement:

The Architect iDigoxin assay is a chemiluminescent microparticle immunoassay (CMIA) used for the quantitative measurement of digoxin concentrations in human serum or plasma.

Digoxin is used in the treatment of mild-to-moderate heart failure as well as chronic atrial fibrillation. The measurement of digoxin concentrations is used to inform treatment decisions and monitor for digoxin toxicity, a known risk of digoxin therapy.

Health Canada is aware of reports of falsely elevated digoxin levels with the CMIA test method in patients receiving enzalutamide, a treatment used for advanced prostate cancer, regardless of active digoxin treatment. Falsely elevated levels of digoxin may lead to unnecessary discontinuation or dose decrease of digoxin, or initiation of therapy for digoxin toxicity.

Health Canada continues to monitor this risk and encourages healthcare providers and laboratories to report any problems or complications associated with the results of the Architect iDigoxin assay.

Key messages for healthcare professionals:

- Be aware of the potential for falsely elevated digoxin levels with the CMIA test method in patients receiving enzalutamide treatment.
- Digoxin levels obtained through the CMIA method should be carefully assessed with appropriate caution when assessing patients receiving enzalutamide treatment.
- In the case of doubtful results, it is recommended to confirm digoxin concentration using an alternative method with no known analytical interference from enzalutamide prior to making any treatment decisions.
- At this time, the Architect iDigoxin assay is the only known assay in Canada impacted by this analytical interference.

In Hong Kong, there are 4 registered pharmaceutical products containing enzalutamide. They are prescription-only medicines. As of the end of April 2026, the Department of Health (DH) had received 23 cases of adverse drug reaction reports related to enzalutamide, but these cases were not related to interference with CMIA laboratory test results of digoxin. Related news was previously issued by the Singapore Health Sciences Authority, and was reported in the Drug News Issue No. 195. The DH issued letters to inform local healthcare professionals to draw their attention on 16 January 2026. In light of the above Health Canada's announcement, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board of Hong Kong.

The United Kingdom: Nasal Decongestant Sprays and Drops Containing Xylometazoline Hydrochloride/Oxymetazoline Hydrochloride: Increased Risk of Rebound Congestion, Rhinitis Medicamentosa, and Tachyphylaxis with Overuse

On 30 April 2026, the Medicines and Healthcare products Regulatory Agency (MHRA) announced that there have been reports of worsening nasal congestion (rebound congestion) when the effects of nasal decongestant sprays or drops containing xylometazoline hydrochloride and oxymetazoline hydrochloride, wear off.

Summary

There have been reports of worsening nasal congestion (rebound congestion) when the effects of nasal decongestant sprays or drops containing xylometazoline hydrochloride and oxymetazoline hydrochloride, referred to hereafter as 'xylometazoline' and 'oxymetazoline', wear off. This typically occurs when these medicines are used for longer than recommended. Continued use can also lead to more serious and longer-lasting changes to the lining and structures of the nose (rhinitis medicamentosa). In addition, repeated use will result in a rapid and noticeable reduction in the medicine's effectiveness (tachyphylaxis).

Patients and caregivers should be informed not to exceed the recommended dose and not to use for more than 5 consecutive days. Continuous use of these medicines for more than 5 days can lead to an increased risk of side effects. Medical advice should be sought if symptoms of nasal congestion persist, worsen or do not improve after 5 days, as alternative treatment may be required.

Advice for Healthcare Professionals:

- rebound congestion, rhinitis medicamentosa, and tachyphylaxis through overuse are recognised side effects with nasal sprays and drops containing xylometazoline or oxymetazoline when used beyond the maximum recommended duration
- patients may mistakenly interpret a rebound congestion effect as a continuation of the original congestion when it is a response to

prolonged use of the product
- advise patients and their caregivers that xylometazoline and oxymetazoline are for short term use only and advise against prolonged or extended use beyond 5 days
- advise patients and their caregivers not to exceed the daily recommended dose and to take note of the minimum dosing interval stated in the product information
- if the symptoms of nasal congestion persist, worsen or do not improve after 5 days, alternative treatment may be required
- patients experiencing rebound congestion or related side effects may feel the need to continue using the products, leading to a cycle of overuse. Opportunistically review patients who may have become reliant on using these products and advise them on how to gradually stop using these medications. Stopping abruptly can worsen symptoms, but patients typically recover within 3 months with early recognition and treatment
- rhinitis medicamentosa is the most serious of these reported effects and is associated with persistent nasal congestion and longer-lasting changes to the nasal mucosa or structures of the nose. Symptoms may not resolve quickly after stopping the decongestant and, in severe cases, may require surgical intervention. Look out for patients presenting with severe nasal congestion and visible changes to the nasal mucosa or other internal nasal structures. Associated symptoms may include nasal irritation or itching, sneezing, and a runny nose. Management may require a tailored treatment plan, including gradual withdrawal of the decongestant, use of alternative therapies, and clinical follow-up to monitor recovery
- use of the nasal sprays or drops containing xylometazoline or oxymetazoline is contraindicated in patients who are taking other oral and nasal forms of sympathomimetic decongestants
- the product information will be transitioning over the next few months towards strengthened warnings regarding these side effects and to advise that they should not be used for more than 5 days

Advice for Healthcare Professionals to Provide to Patients:
- nasal sprays and drops containing xylometazoline and oxymetazoline are used to help clear a blocked nose, caused by cold, flu and allergies
- you can buy these medicines in shops and pharmacies without needing a prescription
- only use these medicines for a short time and to help with your symptoms. You should follow the instructions for use in the Patient Information Leaflet (PIL) and package labelling which comes with the medicine and to not exceed the daily recommended dose and to take note of the minimum time interval between doses
- do not use these medicines for more than 5 consecutive days
- if you use these medicines for longer than the recommended duration, your nose may become blocked again, and you may get other problems such as runny nose, sneezing, itching and irritation on the inside of the nose or your body can stop responding to the medicine
- these side effects may make you feel like you need to keep using the medication to manage your symptoms – talk to a healthcare professional if you are having trouble stopping the medication, or are using for longer or more than recommended
- contact your doctor if your symptoms worsen or you do not feel better after 5 days, as you may need a different treatment
- do not use xylometazoline or oxymetazoline together or with other oral and nasal forms of medicines used to treat a blocked nose, such as pseudoephedrine, phenylephrine or ephedrine
- it is important to read the PIL that comes with your medicine and information on the outer packaging and to talk to a healthcare professional if you experience side effects

Background

Review of rebound congestion, rhinitis medicamentosa, and tachyphylaxis with xylometazoline and oxymetazoline

Xylometazoline and oxymetazoline are sympathomimetic medicines used for the symptomatic relief of nasal and sinus congestion associated with the common cold, sinusitis, and allergic rhinitis in adults and children 6 years and above. They are also used for the treatment of symptoms of flu in adults and children 12 years and above. Xylometazoline is approved for use as a single active substance or in fixed dose combinations with dexpanthenol and ipratropium bromide. Oxymetazoline is approved for use as a single active substance only.

There have been reports of rebound congestion, rhinitis medicamentosa, and tachyphylaxis especially with prolonged or extended use. A review of the available evidence, including the assessment of cumulative reporting of adverse drug reaction reports, was considered by the Cardiovascular, Respiratory, Renal and Allergy Expert Advisory Group (CDRRA EAG) and the Pharmacovigilance Expert Advisory Group (PEAG) of the Commission on Human Medicines (CHM). The EAGs recommended changing the maximum duration of use from 7 days to 5 days in adults and children 12 years and above to align duration of use across all patients for whom these medicines are indicated. The EAGs also recommended updating the Summary of Product Characteristics (SmPC) and PIL to highlight that these medicines are intended for short term use only and that repeated and/or prolonged use can increase the risk of side effects. Additionally, the outer package labelling will also be updated to emphasise the recommended duration of use. The product information will be transitioning over the next few months.

About rebound congestion, rhinitis medicamentosa, and tachyphylaxis

The terms 'rebound congestion' and 'rhinitis medicamentosa' are often used interchangeably, as both describe nasal congestion resulting directly from heavy or prolonged use of nasal decongestant sprays containing xylometazoline and oxymetazoline. Although both conditions cause nasal congestion, they differ in their duration and symptoms.

Rebound congestion is a temporary response that occurs when nasal passages become swollen due to excessive use of nasal decongestant sprays containing xylometazoline and oxymetazoline. The condition is characterised by a 'rebound effect', in which the nasal passages become more congested after the effect of the medication wears off.

Rhinitis medicamentosa is a chronic condition that develops through prolonged or extended use of nasal decongestant sprays. With continued use of these medicines, rebound congestion can worsen and progress to rhinitis medicamentosa, the most serious of these reported effects. The condition is characterised by severe nasal congestion together with visible changes to the nasal mucosa and other internal nasal structures. Additional symptoms may include itchy nasal passages, sneezing, and a runny nose. In severe and untreated cases, this can result in irreversible structural changes within the nasal passages that may require surgical intervention to correct. Unlike other types of rhinitis which may affect the ear, throat, and eyes, rhinitis medicamentosa is confined to the nasal passages. Rebound congestion and rhinitis medicamentosa can lead to a cycle of overuse and dependence on nasal decongestants, where users can feel the need to use more medication to achieve relief.

For both conditions, patients typically fully recover within 3 months with early recognition and treatment. Treatment involves gradually reducing use of the nasal decongestants. Stopping abruptly is not always recommended as this can worsen symptoms of the nasal congestion. Alternative treatment may be required.

Tachyphylaxis refers to an acute sudden decrease in response to a drug after its administration, which leads to rapid onset of drug tolerance. In the context of nasal decongestant sprays and drops, it is a condition where onset begins after a few doses, although the effects of this become apparent after more than 5 days continuous use. It is characterised by a swift decrease in the effectiveness of a medication, which has significant clinical implications as the symptoms of congestion return resulting in the user increasing the frequency and/ or duration of use of their medicine to achieve symptomatic relief from their nasal congestion.

NICE Clinical Knowledge Summaries

For allergic rhinitis, NICE Clinical Knowledge Summaries recommend intranasal corticosteroids and antihistamines – either alone or combined – as first-line therapy for allergic rhinitis, alongside self-management strategies. Intranasal decongestants like xylometazoline should only be considered for short-term use when symptoms persist despite regular corticosteroid treatment or in cases of sudden, severe congestion. While xylometazoline and oxymetazoline can be used for allergic rhinitis, they are not a first-line option and prolonged use should be avoided, as adherence to limits on the stated maximum duration of use can be challenging for some patients.

For common cold, nasal decongestants containing xylometazoline or oxymetazoline are one of the over-the-counter products for the management of nasal congestion recommended within NICE Clinical Knowledge Summaries for adults and children over 6 years of age. However, the guidance has highlighted that prolonged use may

cause rebound congestion, and in severe cases, rhinitis medicamentosa.

In Hong Kong, there are 16 registered pharmaceutical products containing xylometazoline hydrochloride, and 13 registered pharmaceutical products containing oxymetazoline hydrochloride. All products are over-the-counter medicines except one containing steroid, which is a prescription-only medicine. As of the end of April 2026, the Department of Health (DH) had received 19 cases of adverse drug reaction reports with regard to xylometazoline, of which 1 case was reported as rhinitis medicamentosa and none were reported as rebound congestion or tachyphylaxis. The DH had not received any cases of adverse drug reaction reports with regard to oxymetazoline. In light of the above MHRA's announcement, the DH issued letters to inform local healthcare professionals to draw their attention on 4 May 2026, and the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board of Hong Kong.

Drug Recall

Batch Recall of Apo-Fluoxetine Capsules 20mg

On 10 April 2026, the Department of Health (DH) endorsed a licensed drug wholesaler, namely Hind Wing Company Limited (Hind Wing), to recall one batch (batch number: VM4608) of Apo-Fluoxetine Capsules 20mg (Hong Kong registration number: HK-68820), from the market as a precautionary measure due to a potential quality issue.

The DH received notification from Hind Wing that the overseas manufacturer of the product is recalling the above batch due to out of trend degradation product test results. As a precautionary measure, Hind Wing is voluntarily recalling the affected batch from the market.

The above product, containing fluoxetine, is a prescription medicine used for the treatment of depression. According to Hind Wing, the affected batch has been imported into Hong Kong and supplied to private hospitals, private doctors and pharmacies.

As of the end of April 2026, the DH had not received any adverse reaction reports in connection with the above product. A notice was posted in the Drug Office website on 10 April 2026 to alert the public of the product recall. The DH continues to monitor the recall.

Batch Recall of Cinacalcet Tablets 30 mg

On 10 April 2026, the Department of Health (DH) endorsed a licensed drug wholesaler, namely Controlled Medications Limited (CML), to recall a total of two batches (batch number: 4PB0528 and 5PB0173) of the pharmaceutical product, namely Cinacalcet Tablets 30 mg from the market as a precautionary measure due to potential quality issues.

The DH received notification from CML that the overseas manufacturer of the concerned product is recalling the above batches of Cinacalcet Tablets 30 mg as they exceed the accepted level of an impurity, n-nitroso-cinacalcet. N-nitroso-cinacalcet is classified as a probable human carcinogen based on results from laboratory tests. As a precautionary measure, CML voluntarily recalls the affected batches from the market.

The above product, containing cinacalcet, is a prescription only medicine indicated for the treatment of certain parathyroid conditions. The product is not registered in Hong Kong, but was imported for the treatment of particular patients by the Hospital Authority (HA). According to CML, the affect batches were imported into Hong Kong and supplied solely to the HA.

As of the end of April 2026, the DH had not received any adverse reaction reports in connection with the above product. A notice was posted in the Drug Office website on 10 April 2026 to alert the public of the product recall. The DH continues to monitor the recall.

Batch Recall of Genteal Eye Gel

On 28 April 2026, the Department of Health (DH) endorsed a licensed drug wholesaler, namely Healthcare Division O/B DCH Auriga (Hong Kong) Limited (DCH Auriga), the distributor appointed by Alcon Hong Kong Ltd. (Alcon), to voluntarily recall one batch (batch number: 5V83) of the pharmaceutical product, namely Genteal Eye Gel from the market as a precautionary measure due to potential quality issues.

The DH received notification from Alcon that the overseas manufacturer of the product is recalling the above batch of Genteal Eye Gel due to potential

Drug Recall

issues at the manufacturing site that may affect the quality of multidose ophthalmic products.

The above product, containing hydroxypropyl methylcellulose (hypromellose) 0.3% w/w, is an over-the-counter medicine indicated for the treatment dry eye condition. The affected batch of the product is not registered pharmaceutical product, but was imported for the treatment of particular patients by the Hospital Authority (HA). According to Alcon, the affect batch was imported into Hong Kong and supplied solely to the HA.

As of the end of April 2026, the DH had not received any adverse reaction reports in connection with the above product. A notice was posted in the Drug Office website on 28 April 2026 to alert the public of the product recall. The DH continues to monitor the recall.

Drug Incident

Department of Health Clamps Down on Trafficking in Dangerous Drug and Illegal Sale or Possession of Unregistered Anti-obesity Medicine

On 20 April 2026, the Department of Health (DH) announced that in light of the fact that there are people illegally selling or possessing unregistered anti-obesity medicine that is Part 1 poison and prescription drug under the Pharmacy and Poisons Ordinance (Cap. 138), the DH has stepped up inspection and enforcement efforts across Hong Kong in recent days. In collaboration with the Police, five men suspected of violating drug-related laws were arrested and a large quantity of unregistered drugs were seized. These included unregistered anti-obesity drugs labelled in Japanese as containing tirzepatide.

On 17 April 2026, the DH carried out an enforcement operation with the Police to search a registered pharmacy in Sha Tin District. Over 400 tablets of the dangerous drug clonazepam, 20 items of unregistered pharmaceutical products which included six boxes of an unregistered anti-obesity medicine labelled in Japanese as containing tirzepatide, and over 30 other items of controlled medicines, including over 2,700 tablets of zolpidem, were seized. During the operation, four men aged between 25 and 55 were arrested on suspicion of contravention of drug-related offences, including trafficking in a dangerous drug, illegal possession of unregistered pharmaceutical products, and failing to store Part 1 poisons in a locked receptacle, etc.

On 20 April 2026, the DH carried out another enforcement operation with the Police against a registered pharmacy in Jordan, arresting a 36-year-old man. He is suspected of illegally selling an anti-obesity medicine (a Part 1 poison containing tirzepatide as indicated in Japanese on the product labels) and an unregistered pharmaceutical product, as well as failing to store Part 1 poisons in a locked receptable. The operation also resulted in the seizure of 13 boxes of unregistered anti-obesity medicine labelled in Japanese as containing tirzepatide.

Tirzepatide is used for the treatment of obesity, and its side effects include vomiting, nausea and diarrhoea. Medicines containing tirzepatide, zolpidem, and clonazepam are Part 1 poisons and prescription drugs under the Pharmacy and Poisons Ordinance, should be used under a doctor's direction and must be supplied on the premises of a registered pharmacy under the supervision of a registered pharmacist upon a doctor's prescription. Furthermore, clonazepam is a dangerous drug regulated under the Dangerous Drugs Ordinance (Cap. 134).

The DH investigations continue. The DH emphasised that it has an established mechanism to monitor the sale of pharmaceutical products in the market (including the Internet). If the DH detects any suspected illegal sale or possession of pharmaceutical products, Part 1 poisons or dangerous drugs, the DH will promptly investigate, and, if necessary, refer the case to other law enforcement agencies to follow up, or conduct joint operations with other law enforcement agencies, and any irregularities so found will be dealt with in accordance with the law.

A press release was posted in the Drug Office website on 20 April 2026 to alert the public of the drug incident.

A product containing any western drug ingredient must be registered under the Pharmacy and Poisons Ordinance before it can be sold in Hong Kong. Part 1 poisons should be sold at registered pharmacies under the supervision of registered pharmacists. Illegal sale or possession of Part 1 poisons and unregistered pharmaceutical products are offences under the Pharmacy and Poisons Ordinance (Cap. 138). The maximum penalty is a fine of $100,000 and two years' imprisonment for each offence. Antibiotics can only be supplied at registered pharmacies by registered pharmacists or under their supervision and upon a doctor's prescription. They should only be used under the advice of a doctor. Illegal sale or possession of antibiotics are offences under the Antibiotics Ordinance (Cap. 137) and the maximum penalty is a $50,000 fine and one year's imprisonment for each offence.

Under the Import and Export Ordinance (Cap. 60), pharmaceutical products must be imported or exported under and in accordance with an import or export licence issued under the Import and Export Ordinance. Illegal import or export of pharmaceutical products are offences under the Import and Export Ordinance (Cap. 60) and the maximum penalty is a fine of $500,000 and 2 years' imprisonment.

All registered pharmaceutical products should carry a Hong Kong registration number on the package in the format of "HK-XXXXX". The products mentioned in the above incidents were not registered pharmaceutical products under the Ordinance in Hong Kong. Their safety, quality and efficacy cannot be guaranteed. Members of the public were exhorted not to use products of unknown or doubtful composition. They should stop using the aforementioned products immediately if they had them in their possession and to consult healthcare professionals if they felt unwell after taking the products. The products should be destroyed or disposed properly, or submitted to the Department's Drug Office during office hours.

Update on Drug Office's website: You can now search the newly registered medicines in the past year at http://www.drugoffice.gov.hk/eps/drug/newsNRM60/en/healthcare_providers?pageNoRequested=1.
Details of ALL registered pharmaceutical products can still be found in the Drug Office website at http://www.drugoffice.gov.hk/eps/do/en/healthcare_providers/news_informations/

Useful Contact

Drug Complaint:
Tel: 2572 2068
Fax: 3904 1224
E-mail: pharmgeneral@dh.gov.hk

Adverse Drug Reaction (ADR) Reporting:
Tel: 2319 2920
Fax: 2319 6319
E-mail: adr@dh.gov.hk
Link: http://www.drugoffice.gov.hk/adr.html
Post: Clinical Trials and Pharmacovigilance Unit,
Drug Office, Department of Health,
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The purpose of Drug News is to provide healthcare professionals with a summary of local and overseas drug safety news released. Healthcare professionals are advised to keep update with the information and provide corresponding advice or therapeutic measure to patients and public.