Drug News
藥 物 情 報

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This is a monthly digest of local and overseas drug safety news released by the Drug Office of the Department of Health in March 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

The United States: FDA Is Requiring Warning about Vitamin B6 Deficiency and Associated Seizures for Drug Products Containing Carbidopa/Levodopa

On 20 March 2026, the U.S. Food and Drug Administration (FDA) announced that application holders for all drug products containing carbidopa/levodopa had been notified that the Agency is requiring the addition of a warning, and corresponding revisions, to the prescribing information to state that these medications, approved to treat symptoms of Parkinson's disease, can cause vitamin B6 deficiency and vitamin B6 deficiency-associated seizures. The warning directs healthcare professionals to evaluate baseline vitamin B6 levels prior to starting patients on treatment with carbidopa/levodopa therapies and periodically while on treatment and to supplement with vitamin B6 as necessary.

What Are Drug Products Containing Carbidopa/Levodopa?

Drug products containing carbidopa/levodopa are approved to treat symptoms of Parkinson's disease, a progressive nervous system disorder. Levodopa is the metabolic precursor to dopamine, a neurotransmitter in the brain that declines in patients with Parkinson's disease, leading to motor symptoms such as tremors, rigidity and bradykinesia (slow movements). Carbidopa inhibits the decarboxylation of peripheral levodopa, making more levodopa available for delivery to the brain.

Drug products containing carbidopa/levodopa approved to treat symptoms of Parkinson's disease may contain both carbidopa and levodopa (trade names: Crexont, Dhivy, Duopa, Rytary, Sinemet, and Sinemet CR); carbidopa/levodopa/entacapone (trade name: Stalevo); or foscarbidopa/foslevodopa (trade name: Vyalev), which is converted to active carbidopa/levodopa in the body. These products are available in multiple formulations and may be administered by several different routes, including oral tablets, an enteral (intestinal) suspension, and a subcutaneous injection for continuous infusion.

Drug products containing carbidopa/levodopa can deplete vitamin B6 levels during the process by which levodopa is converted to dopamine. Additionally, carbidopa binds to the active form of vitamin B6, which creates additional functional loss of vitamin B6.

What Should Patients and Caregivers Do?

Patients and caregivers should be aware that taking drug products containing carbidopa/levodopa can lead to vitamin B6 deficiency, which can increase the risk of seizures. To monitor for vitamin B6 deficiency, your healthcare professional should evaluate your vitamin B6 levels before starting treatment with a drug product containing carbidopa/levodopa, periodically during treatment, and if symptoms of vitamin B6 deficiency appear during treatment. These symptoms include seizures, as well as depression; confusion; inflammation of the lips, tongue, and skin; and nerve damage causing numbness, tingling, sharp pain, or muscle weakness. Patients should take vitamin B6 supplements as recommended in consultation with a healthcare professional.

Higher doses of carbidopa/levodopa may increase the risk of vitamin B6 deficiency. Many of the cases of seizures reported with carbidopa/levodopa use did not respond to traditional anti-seizure medications but resolved after vitamin B6 administration.

What Should Healthcare Professionals Do?

Healthcare professionals should evaluate vitamin B6 levels before starting patients on treatment with

drug products containing carbidopa/levodopa, periodically during treatment, and if symptoms of vitamin B6 deficiency appear during treatment. Healthcare professionals should consider whether vitamin B6 supplementation is necessary. Higher doses of carbidopa/levodopa may increase the risk of vitamin B6 deficiency.

Healthcare professionals should be aware that seizures associated with the use of a product containing carbidopa and levodopa do not respond to traditional anti-seizure medications but resolve after vitamin B6 administration. Furthermore, select anti-seizure medications may further worsen a vitamin B6 deficiency. Healthcare professionals should inform patients of these risks.

What Did FDA Find?

FDA conducted a safety review and identified 14 cases of seizures linked to vitamin B6 deficiency in patients using drug products containing carbidopa/levodopa. The 14 cases included postmarketing reports submitted to FDA (13 reports) or found in the medical literature (1 report), so there are likely additional cases about which we are unaware. All of the reviewed cases involved levodopa doses exceeding 1,000 mg daily, with higher doses (>1,500 mg levodopa) associated with shorter duration from treatment initiation to identification of vitamin B6 deficiency. The seizure cases were split among oral formulations and an enteral suspension, with latency periods ranging from 23 to 132 months. The seizures have typically presented as focal onset seizures with secondary generalization, consistent with seizures observed with vitamin B6-dependent epilepsy, and progression to status epilepticus was observed in some cases, indicating an urgent need for rapid identification and treatment.

In these cases of reported seizures, there was additional clinical evidence supportive of vitamin B6 deficiency, including elevated homocysteine levels in four cases, microcytic or normocytic anemia in three cases, and neuropsychiatric symptoms in four cases. Of the 9 patients treated with vitamin B6 supplementation, all 9 had resolution of their seizures, despite the majority of these patients previously demonstrating a lack of response to multiple antiseizure medications. Two fatalities occurred, both with documented low vitamin B6 levels and poorly controlled seizures.

The review found no cases of vitamin B6-associated seizures associated with carbidopa/levodopa/entacapone products or with the injectable carbidopa/levodopa product, which may reflect lower usage patterns, more recent approval dates, and/or different dosing and administration requirements. However, biological plausibility suggests there may be a similar risk across all drug products containing carbidopa/levodopa, as vitamin B6 deficiency was also observed in the clinical trials that supported the original approval of the injectable carbidopa/levodopa product. Based on the available data, FDA concluded there is reasonable evidence of a causal association between drug products containing carbidopa/levodopa and vitamin B6 deficiency-associated seizures.

In Hong Kong, Vyalev containing foscarbidopa/foslevodopa is not a registered pharmaceutical product, while there are registered pharmaceutical products containing carbidopa and levodopa including carbidopa/levodopa (8 products), carbidopa/levodopa/entacapone (8 products) and levodopa/benserazide (3 products). All products are prescription-only medicines. As of the end of March 2026, the Department of Health (DH) had received one case of adverse drug reaction report with regard to carbidopa/levodopa and levodopa/benserazide; and one case with regard to levodopa/benserazide, but these cases were not reported as vitamin B6 deficiency or vitamin B6 deficiency-associated seizures. In light of the above FDA's announcement, the DH issued letters to inform local healthcare professionals to draw their attention on 23 March 2026, and the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board of Hong Kong .

Canada: Summary Safety Review: Bortezomib: Assessing the potential risk of drug reaction with eosinophilia and systemic symptoms

On 26 March 2026, Health Canada issued the following announcement:

Product

Bortezomib-containing products

Potential Safety Issue

Drug reaction with eosinophilia and systemic symptoms (DRESS), a type of allergic drug reaction with rash, fever, increased white blood cell count, and injury to 1 or more organs

Key Messages

- Health Canada's safety review found a possible link between the use of bortezomib and the risk of DRESS.
- Health Canada will work with the manufacturers to update the product safety information in the Canadian product monograph (CPM) for all bortezomib-containing products to include the risk of DRESS. Health Canada will also inform healthcare professionals about this update through a Health Product InfoWatch communication.

Overview

Health Canada reviewed the potential risk of DRESS with the use of bortezomib. The safety review was triggered by a notification of foreign action received from a manufacturer.

Use in Canada

- Bortezomib is a prescription drug authorized for sale in Canada to treat adults with multiple myeloma (cancer that forms in a type of white blood cell called a plasma cell) and mantle cell lymphoma (an aggressive type of non-Hodgkin lymphoma, a cancer that affects a type of white blood cells called B lymphocytes, which are part of the immune system).
- Bortezomib has been marketed in Canada since 2005, under the brand name Velcade. It is currently available as a lyophilized (freeze-dried) powder or liquid. Generic versions are also available.

Safety Review Findings

- Health Canada reviewed the available information provided by a manufacturer, as well as from searches of the Canada Vigilance database and the scientific literature.
- At the time of the review, Health Canada had not received any Canadian reports of DRESS in patients treated with bortezomib.
- Health Canada reviewed 29 international cases of DRESS in patients treated with bortezomib. Although the use of other medications was a confounder (other factor that may have been responsible for the occurrence of DRESS) in all 29 cases, 27 of those cases were found to be possibly linked to the use of bortezomib. Two of the 29 cases were unlikely to be linked. One death was reported among the 29 cases reviewed, which was possibly linked to the use of bortezomib.
- Health Canada also reviewed 1 article published in the scientific literature. Due to important limitations regarding the design and analysis of the study, the evidence did not strongly support a link between the use of bortezomib and the risk of DRESS.

Conclusions and Actions

- Health Canada's review found a possible link between the use of bortezomib and the risk of DRESS.
- Health Canada will work with the manufacturers to update the CPM for all bortezomib-containing products to include the risk of DRESS.
- Health Canada will also inform healthcare professionals about this update through a Health Product InfoWatch communication.
- Health Canada will continue to monitor safety information involving bortezomib, 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 13 registered pharmaceutical products containing bortezomib. All products are prescription-only medicines. As of the end of March 2026, the Department of Health (DH) had received 20 cases of adverse drug reaction report with regard to bortezomib, but these cases were not related to DRESS. In light of the above Health Canada's announcement, the DH issued letters to inform local healthcare professionals to draw their attention on 27 March 2026, and the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board of Hong Kong .

Drug Recall

Total Recall of Tazverik Tablets 200mg

On 9 March 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 the holder of certificate of drug registration, Hutchmed (Hong Kong) Limited O/B Hutchmed (Hong Kong) Limited (Hutchmed), to voluntarily recall one registered pharmaceutical product, namely Tazverik Tablets 200mg (Hong Kong Registration number: HK-68216) from the market due to potential safety risks.

The DH received notification from Hutchmed that the overseas manufacturer of the product is recalling Tazverik Tablets due to ongoing clinical trial data indicating an increased risk of secondary haematologic malignancies, where the potential risks may outweigh the therapeutic benefits. Therefore, Hutchmed voluntarily recalls the above product from the market.

The above product, containing tazemetostat, is a prescription medicine indicated for the treatment of blood cancer. According to Hutchmed, the above product was imported into Hong Kong and distributed by DCH Auriga and has been supplied to the Hospital Authority, local private hospitals, private doctors and exported to Macau.

As of the end of March 2026, the DH had received one adverse reaction report associated with one batch (batch no. 3225173) of the product, but the case was not related to secondary haematologic malignancies. A notice was posted in the Drug Office website on 9 March 2026 to alert the public of the product recall. The DH noted that the recall was completed.

Drug Incident

Department of Health cracks down on illegal online sale of controlled anti-obesity medicine

On 4 March 2026, the Department of Health (DH) discovered suspected illegal online sale of a controlled anti-obesity medicine and carried out an enforcement operation with the Police in Mong Kok district, a 30-year-old woman suspected of illegally selling Part 1 poisons and unregistered pharmaceutical products was arrested.

Following up on a complaint, the DH obtained the anti-obesity medicine via an instant messaging application. The label of the product, written in Japanese, indicated that it contained tirzepatide, a substance classified as Part 1 poison under the Pharmacy and Poisons Ordinance (Cap. 138) (PPO).

The product is suspected to be an unregistered pharmaceutical product in Hong Kong. The DH will continue to investigate the incident.

Tirzepatide is used for the treatment of obesity, and its side effects include hair loss, nausea and diarrhoea. Medicines containing tirzepatide should be used under a doctor's direction and must be supplied on the premises of an Authorized Seller of Poisons (commonly known as a pharmacy) under the supervision of a registered pharmacist upon a doctor's prescription.

The DH strongly urged members of the public not to self-purchase or consume products of doubtful composition or from unknown sources. Purchasing controlled medicines (including slimming drugs) online poses health risks. Besides the lack of a doctor's assessment of an individual's health condition, it is difficult to ascertain the legitimate source of the drugs. It is also impossible to know whether the drugs were properly stored during transportation (especially for drugs requiring cold-chain storage). This leaves their safety, quality and efficacy unguaranteed.

A press release was posted in the Drug Office website on 4 March 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
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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.