Australia: Medicine Safety Update: Medicines containing vitamin B6 (pyridoxine, pyridoxal or pyridoxamine)

The Therapeutic Goods Administration (TGA) announces some dosages to be rescheduled as Pharmacist Only Medicines.

Summary
Oral preparations containing more than 50 mg but not more than 200 mg per recommended daily dose of vitamin B6 will be rescheduled as Pharmacist Only Medicines from 1 June 2027.

Vitamin B6 is also known as pyridoxine, pyridoxal, or pyridoxamine.

The effect of TGA's decision is that from 1 June 2027 products with low doses of vitamin B6 will continue to be available for general sale, while products containing higher doses will require advice from a pharmacist or a prescription from a doctor, depending on the dose:

- oral preparations containing **50 mg or less per recommended daily dose** will continue to be available for general retail sale.
- oral preparations containing **more than 50 mg but not more than 200 mg per recommended daily dose** will be available over the counter with the advice of a pharmacist.
- oral preparations containing **more than 200 mg per recommended daily dose** will continue to require a prescription.

Vitamin B6 can cause peripheral neuropathy, and while the risk is greatest for higher intakes of vitamin B6, it cannot be excluded for doses less than 50 mg/day. It can be difficult for consumers to estimate their vitamin B6 intake because of the widespread presence of vitamin B6 in listed medicines and food supplements and the different ways vitamin B6 is labelled on products.

The scheduling for vitamin B6 intersects with other regulatory controls which also require changes following the scheduling decision. Additional recommendations for improved consumer safety are also under consideration. The rescheduling implementation date of 1 June 2027 allows for necessary regulatory and industry changes.

What health professionals should do
While the implementation date for these regulatory changes is not until 1 June 2027, health professionals can take action now to consider vitamin B6 toxicity in patients presenting with symptoms of peripheral neuropathy.

A review of the patient's vitamin B6 intake is recommended, paying close attention to potential sources such as B vitamins, multivitamins and magnesium and zinc products, particularly when taken in combination. Various food and beverages supplemented with vitamin B6 should also be taken into consideration when estimating a person's total vitamin B6 intake.

Health professionals should be alert to the paradox that the most common symptoms associated with vitamin B6 toxicity are similar to those of vitamin B6 deficiency. Therefore, it is important to be aware that consumers may inadvertently exacerbate the symptoms they are trying to treat by taking supplements containing vitamin B6.

Adverse event reports submitted toTGA suggest there is a lack of awareness that vitamin B6 can cause peripheral neuropathy. Most consumers who use complementary medicines perceive these medicines to be safe and effective.

Adverse event reports also suggest a lack of awareness about the presence of vitamin B6 in medicines, particularly if the label lists the chemical name without the common name 'vitamin B6'. Health professionals should be alert to this as consumers may not recall use if asked, leading to delayed diagnosis and medicine cessation.

Following the scheduling decision, TGA is considering recommendations on ways to make it clearer for consumers that vitamin B6 is present and how much is in the medicine.

There are currently three forms of vitamin B6 in low-risk products available in the Australian market through self-selection:

- pyridoxine hydrochloride
- pyridoxal 5-phosphate
- pyridoxal 5-phosphate monohydrate.

When included as active ingredients, pharmaceutical companies must list these names on the label.

Where a label is not available for the medicine, formulation details of medicines that can be supplied within Australia can be found by searching the Australian Register of Therapeutic Goods (ARTG). The available PDF summary will list the vitamin B6 ingredient, if present, using one of the above names and state how much is in the medicine as the equivalent amount of pyridoxine.

Background

Vitamin B6 is a water-soluble vitamin that acts as a co-enzyme in more than 150 enzymatic reactions in the metabolism of amino acids, carbohydrates and lipids. Vitamin B6 is also important for the synthesis of many neurotransmitters, haemoglobin formation and immune functions. Vitamin B6 deficiency can cause peripheral neuropathy, seborrheic dermatitis (scaly, flaky, and sometimes itchy patches of skin), glossitis (inflammation of the tongue), and cheilosis (inflammation, cracking, and sores at the corners of the mouth), and, in adults, confusion and seizures.

In Australia, the estimated average requirement for vitamin B6 for adults is 1.1 to 1.3 mg/day and the recommended dietary intake (RDI) is 1.3 to 1.7 mg/day. Vitamin B6 is found in a wide range of foods including meats, breakfast cereals, vegetables and fruits and the RDI is easily met through dietary intake alone for most Australians. Clinical deficiency of vitamin B6 is rare.

Peripheral neuropathy is a known side effect of vitamin B6 toxicity and is characterised by tingling, burning, or numbness, usually in the hands or feet. Delayed diagnosis and continued exposure can lead to progression of the disease.

Because of this risk, since 1 March 2022, medicines containing daily doses of vitamin B6 over 10 mg or equivalent have been required to carry the following statement:

> "WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. (Contains vitamin B6)"

This label warning was previously only required for daily doses of vitamin B6 over 50 mg. During the transition period, TGA published a Medicine Safety Update (MSU) article warning that vitamin B6 can cause peripheral neuropathy. Following the implementation of the label warning statement at daily doses above 10 mg, TGA continued to monitor any emerging evidence and reports of adverse events related to this issue.

An application to amend the Poisons Standard in relation to vitamin B6 was referred to the Advisory Committee on Medicines Scheduling (ACMS) in November 2024. TGA released an interim decision on 26 June 2025.

Following public consultation, we released the final decision on 25 November 2025.

A wide range of materials was considered in making the scheduling change including:
- advice received from the ACMS
- 21 public submissions received in response to consultation before the ACMS meeting
- the interim decision and the materials considered as part of this, as published on 26 June 2025
- 248 submissions received in response to the public consultation on the interim decision

At the time of the final decision, there were at least 125 medicines on the Australian market providing more than 50 mg but not more than 200 mg vitamin B6 per maximum recommended daily dose. Of these, 116 were listed complementary medicines. These ARTG listed medicine entries will be cancelled. To continue to be available on the Australian market, applications must be made for their evaluation as registered medicines.

Adverse events reported to us

The scheduling decision-maker considered adverse events as part of the relevant information. From the final decision document, as of 31 October 2025, there were 250 reports of peripheral neuropathy, peripheral sensory neuropathy, peripheral sensorimotor neuropathy, small fibre neuropathy, polyneuropathy or chronic polyneuropathy for products containing vitamin B6 on the TGA's Database of Adverse Event Notifications (DAEN).

Of these, 152 also reported ‘Hypervitaminosis B6’ and/or ‘Vitamin B6 increased’. There were another 162 reports of ‘Hypervitaminosis B6’ and/or ‘Vitamin B6 increased’ with less specific reaction terms such as paraesthesia, burning sensation etc. possibly suggestive of neuropathies.

Please refer to the following website in TGA for details:
https://www.tga.gov.au/news/safety-updates/medicines-containing-vitamin-b6-pyridoxine-pyridoxal-or-pyridoxamine

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. So far, the Department of Health (DH) has 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 posted on the Drug Office website on 5 May 2020, 5 Oct 2022 and 15 May 2023. Letters to inform local healthcare professionals were issued by DH on 5 Oct 2022. In Dec 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 TGA announcement “Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible (Contains vitamin B6)”. DH will remain vigilant on any safety update of the drugs issued by other drug regulatory authorities.

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