Medicines Adverse Reactions Committee

Meeting date	12/03/2026	Agenda item	3.2.2
Title	**Pyridoxine (Vitamin B6) safety review**		
Submitted by	Medsafe Pharmacovigilance Team	Paper type	For advice
Active ingredient Pyridoxine Pyridoxal Pyridoxamine	**Product name** See Table 3 for medicinal products	**Sponsor**	
PHARMAC funding	See Table 9		
Previous MARC meetings	None		
International action	Australia – rescheduling and warning labels		
Prescriber Update	Vitamin B6 (pyridoxine) and peripheral neuropathy (June 2025)		
Classification	Prescription in medicines with >200mg per recommended daily dose General sale in medicines ≤200mg per recommended daily dose. Dietary supplement if no therapeutic claims are made and no therapeutic purpose is intended or implied and meets the requirements of the Dietary Supplements Regulations.		
Usage data	See Table 10		
Advice sought	**The Committee is asked to advise:** • Are there any safety concerns with pyridoxine-containing products? – If yes, is any regulatory action required? • Is there a risk of serious side effects from pyridoxine-containing products available at doses without a prescription? – If yes, is any regulatory action required?		

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1 PURPOSE

This paper reviews suspected adverse drug reactions (ADRs) reported in New Zealand for pyridoxine-containing medicines and dietary supplements. This follows regulatory action in Australia due to safety concerns, and cases of peripheral neuropathy associated with pyridoxine reported in New Zealand.

[redacted]

2 BACKGROUND

Vitamin B6 is a water-soluble, essential nutrient found in food [1]. The three natural forms are pyridoxine, pyridoxal, and pyridoxamine. Vitamin B6 is commonly present in dietary supplements, such as multivitamin and mineral preparations and vitamin B complexes, often in combination with magnesium or zinc.

The background section of this paper:

- provides the recommended dietary intake for pyridoxine
- summarises the classification of pyridoxine when used as a medicine and a dietary supplement
- provides the approved pyridoxine-containing medicinal products available in New Zealand
- provides the known safety concerns as per the medicine data sheets
- gives a brief overview of some dietary supplements marketed in New Zealand
- provides funding and usage data for medicines and dietary supplements
- describes the regulatory action in Australia.

2.1 Recommended dietary intake

Table 1 provides the vitamin B6 nutrient reference values for Australia and NZ.

Clinical deficiency is rare. The symptoms of vitamin B6 deficiency include seborrhaeic dermatitis, microcytic anaemia, convulsions and depression and confusion [2].

Table 1: Vitamin B6 (as pyridoxine) nutrient reference values by life stage and gender

Life stage/gender	Age	EAR[a] mg/day	RDI[b] mg/day	UL[c] mg/day
Infants	0–6 months	-	0.1 (AI[d])	Unknown[e]
	7–12 months	-	0.3 (AI[d])	
Children	1–3 years	0.4	0.5	15
	4–8 years	0.5	0.6	20
Boys	9–13 years	0.8	1.0	30
	14–18 years	1.1	1.3	40
Girls	9–13 years	0.8	1.0	30
	14–18 years	1.0	1.2	40
Adult Men	19–30 years	1.1	1.3	50
	31–50 years	1.1	1.3	50
	51–70 years	1.4	1.7	50
	>70 years	1.4	1.7	50
Adult Women	19–30 years	1.1	1.3	50
	31–50 years	1.1	1.3	50
	51–70 years	1.3	1.5	50
	>70 years	1.3	1.5	50
Pregnancy	14–18 years	1.6	1.9	40
	19–50 years	1.6	2.0	50
Lactation	14–18 years	1.7	2.0	40
	19–50 years	1.7	2.0	50

a. EAR = Estimated Average Requirement: A daily nutrient level estimated to meet the requirements of half the healthy individuals in a particular life stage and gender group.
b. RDI = Recommended Dietary Intake: The average daily dietary intake level that is sufficient to meet the nutrient requirements of nearly all (97–98 per cent) healthy individuals in a particular life stage and gender group.
c. UL = Upper Level of Intake: The highest average daily nutrient intake level likely to pose no adverse health effects to almost all individuals in the general population. As intake increases above the UL, the potential risk of adverse effects increases.
d. AI = Adequate Intake (used when an RDI cannot be determined): The average daily nutrient intake level based on observed or experimentally-determined approximations or estimates of nutrient intake by a group (or groups) of apparently healthy people that are assumed to be adequate.
e. It is not possible to establish the upper limit for infants. The source of intake should be breast milk, formula or food only.

Source: National Health and Medical Research Council and Australian Government Department of Health and Ageing and New Zealand Ministry of Health. 2006. *Nutrient Reference Values for Australia and New Zealand* URL: https://www.nhmrc.gov.au/sites/default/files/images/nutrient-refererence-dietary-intakes.pdf (accessed 2 May 2025).

Comments

For adults, the recommended dietary intake is only 1.3mg/day, which increases slightly in older age. The RDI is slightly higher again in pregnancy and lactation. The recommended upper limit for adults is 50mg/day. Children's RDI and UL are much lower than adults.

The NHMRC has announced that it will be revising the vitamin B6 upper limit, with public consultation expected in mid-2026.

2.2 Classification

Vitamin B6/pyridoxine is regulated as a medicine and as a dietary supplement in New Zealand.

2.2.1 When used as a medicine

When used as a medicine (ie, for a therapeutic purpose), the Medicines Regulations 1984 schedule pyridoxal, pyridoxamine and pyridoxine as prescription medicines, except in medicines containing 200mg or less per recommended daily dose (Table 2).

Therefore, the maximum upper limit for general sales medicines containing vitamin B6 is 200mg/day.

Table 2: Classification of pyridoxine, pyridoxal and pyridoxamine in New Zealand

Ingredient	Conditions (if any)	Classification
Pyridoxal	in medicines containing more than 200 milligrams per recommended daily dose	Prescription
Pyridoxal	in medicines containing 200 milligrams or less per recommended daily dose	General Sale
Pyridoxamine	in medicines containing more than 200 milligrams per recommended daily dose	Prescription
Pyridoxamine	in medicines containing 200 milligrams or less per recommended daily dose	General Sale
Pyridoxine	in medicines containing more than 200 milligrams per recommended daily dose	Prescription
Pyridoxine	in medicines containing 200 milligrams or less per recommended daily dose	General Sale

Source: Medsafe Classification Database, accessed 2 February 2026.

Comment

Note that 200mg of pyridoxine is 15,000% of the recommended dietary intake (1.3mg).

2.2.2 When used as a dietary supplement

Dietary supplements are regulated under the Food Act 2014 (administered by the Ministry of Primary Industries) and are subject to the Dietary Supplements Regulations 1985 (DSR; administered by Medsafe).

Regulation 2A of DSR defines a dietary supplement as follows:

> **2A Meaning of dietary supplement**
>
> (1) In these regulations, **dietary supplement** means something to which subclauses (2) to (6) apply.
>
> (2) It is an amino acid, edible substance, herb, mineral, synthetic nutrient, or vitamin.
>
> (3) It is sold by itself or in a mixture.
>
> (4) It is sold in a controlled dosage form as a liquid, powder, or tablet (which might be described on the label as a cachet, capsule, lozenge, or pastille instead of as a tablet).
>
> (5) It is intended to be ingested orally.
>
> (6) It is intended to supplement the amount of the amino acid, edible substance, herb, mineral, synthetic nutrient, or vitamin normally derived from food.

Regulation 3 specifies the maximum daily doses for certain minerals and vitamins. Although vitamin B6/pyridoxine is described in section 18 of the DSR, section 3 does not specify a maximum daily dose.

Regulations 4–10 provide labelling requirements for dietary supplements. Among the requirements, labels must specify that the product is a dietary supplement, include the quantities of the active and inactive ingredients, and include the recommended daily dose (quantity and frequency and must not exceed the maximum dose permitted by regulation 3). Regulation 5(1)(i) states that the label must include a warning in any case where a danger exists if an overdose is taken.

Dietary supplements must not make therapeutic claims, as per Regulation 11.

11 Therapeutic claims

Except as permitted by the Medicines Act 1981 and any regulations made under that Act, no dietary supplement or package or container containing a dietary supplement shall be advertised or labelled with a statement relating to any of the following matters:

(a) treating or preventing disease:

(b) diagnosing disease or ascertaining the existence, degree, or extent of a physiological condition:

(c) altering the shape, structure, size, or weight of the human body:

(d) otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating or reducing or postponing, or increasing or accelerating, the operation of that function, or in any other way.

[redacted]

2.3 Medicines: Products, data sheet information

2.3.1 Products

Table 3 provides the currently approved pyridoxine-containing products in New Zealand, including their classification and indications. Note that some of these products are classified as pharmacy only or prescription, due to the other active substances contained in the product. Pyridoxine is generally used to treat vitamin B6 deficiency or supplement dietary intake during pregnancy and lactation.

Table 3: Currently approved pyridoxine containing medicinal products, their dose form, active ingredients, classification and approved indication(s)

Trade Name, Dose form	Active ingredient(s), including pyridoxine form and quantity	Classification	Approved indication(s)
Cernevit Powder for injection	Ascorbic acid + Biotin + Cocarboxylase tetrahydrate+ Colecalciferol + Cyanocobalamin + Dexpanthenol + dl-Alpha tocopherol + Folic acid + Nicotinamide + **Pyridoxine hydrochloride 5.5mg**+ Retinol palmitate + Riboflavin sodium phosphate	General sale	Indicated in adults and children over 11 years of age requiring parenteral multivitamins supplementation to correct or prevent vitamin deficiencies when oral administration is contraindicated, impossible or insufficient.
Elevit (Bayer IU 1613794) Film coated tablet	Ascorbic acid + Biotin + Calcium hydrogen phosphate + Calcium pantothenate + Colecalciferol + Copper sulfate + Cyanocobalamin + DL-Alpha tocopherol + Ferrous bisglycinate + Folic acid + Magnesium oxide + Levomefolate calcium + Manganese sulfate + Nicotinamide + Potassium iodide + **Pyridoxine hydrochloride 2.54mg (equivalent to 1.90mg vitamin B6)**+ Riboflavin +Sodium selenite + Thiamine nitrate + Zinc citrate trihydrate	Pharmacy only	To supplement maternal dietary intake during pregnancy and lactation.
Elevit (new formulation) Film coated tablet	Ascorbic acid + Biotin + Calcium hydrogen phosphate + Calcium pantothenate + Colecalciferol + Copper sulfate + Cyanocobalamin + DL-Alpha tocopherol + Ferrous fumarate + Folic acid + Magnesium oxide + Manganese sulfate monohydrate + Nicotinamide + Potassium iodide + **Pyridoxine hydrochloride 2.31mg** + Riboflavin + Sodium selenite + Thiamine nitrate+ Zinc citrate trihydrate	Pharmacy only	To supplement maternal dietary intake during pregnancy and lactation.
Elevit (vitamin D) Film coated tablet	Ascorbic acid + Biotin + Calcium hydrogen phosphate + Calcium pantothenate + Colecalciferol + Copper sulfate + Cyanocobalamin + DL-Alpha tocopherol + Ferrous fumarate + Folic acid + Magnesium oxide + Manganese sulfate monohydrate+ Nicotinamide + Potassium iodide + **Pyridoxine hydrochloride 2.31mg** + Riboflavin + Sodium selenite + Thiamine nitrate + Zinc citrate hydrate	Pharmacy only	To supplement maternal dietary intake during pregnancy and lactation.
Pabrinex Concentrate for infusion, combination pack	Ampoule 1 (5mL): Ascorbic acid + Glucose monohydrate+ Nicotinamide Ampoule 2 (5mL): **Pyridoxine hydrochloride 10 mg/mL (50mg/ampoule)**+ Riboflavin sodium phosphate + Thiamine hydrochloride	Prescription	Indicated in adults and children for rapid therapy of severe depletion or malabsorption of the water soluble vitamins B and C: • particularly in alcoholism, where a severe depletion of thiamine can lead to Wernicke's encephalopathy • after acute infections • post-operatively • in psychiatric states Also used to maintain levels of vitamin B and C in patients on chronic intermittent haemodialysis.

Trade Name, Dose form	Active ingredient(s), including pyridoxine form and quantity	Classification	Approved indication(s)
Pyridoxine multichem Tablet	**Pyridoxine hydrochloride 50mg (+1.8% (0.9mg) overage)**	General sale	Prevention and management of vitamin B6 deficiency. Treatment of sideroblastic anaemias, homocystinuria or primary hyperoxaluria. Vitamin B6 dependency in infants. Pyridoxine has been widely used in premenstrual syndrome despite controversy over its effectiveness.
Soluvit N Powder for injection	Biotin + Cyanocobalamin + Folic acid + Nicotinamide + **Pyridoxine hydrochloride 4.9 mg** (**corresponding to Vitamin B6 4.0 mg**)+ Riboflavin sodium phosphate + Sodium ascorbate + Sodium pantothenate + Thiamine nitrate	General sale	Intended as a supplement in intravenous nutrition in order to meet the daily requirements of the water-soluble vitamins in adults, children, infants and neonates. Fat-soluble vitamins should also be administered to patients receiving prolonged parenteral nutrition.
Syndrex Concentrate for infusion (Provisional consent to meet supply issues)	Ampoule 1: **Pyridoxine hydrochloride 10 mg/mL**+ Riboflavin sodium phosphate + Thiamine hydrochloride Ampoule 2: Ascorbic acid + Glucose monohydrate + Nicotinamide	Prescription	Indicated in adults and children for rapid therapy of severe depletion or malabsorption of the water soluble vitamins B and C: • particularly in alcoholism, where a severe depletion of thiamine can lead to Wernicke's encephalopathy • after acute infections • post-operatively • in psychiatric states Also used to maintain levels of vitamin B and C in patients on chronic intermittent haemodialysis.

Source: Medsafe Product Application Search, accessed 30 January 2026.

2.3.1.1 Unapproved indications

Pyridoxine is also used for the following unapproved indications [3]:

- prophylaxis of cycloserine-induced neuropathy
- treatment of isoniazid-induced neuropathy
- prophylaxis of isoniazid-induced neuropathy
- prophylaxis of nausea in pregnancy.

[redacted]

2.3.2 Data sheets

Table 4 provides the relevant safety information from the data sheets. [redacted]

Table 4: Pyridoxine-containing medicines: safety information from the data sheets

Product name (pyridoxine quantity per dose form)	**Safety information**
Pyridoxine multichem tablet (50mg)	**4.4 Warnings** Vitamin B6 is relatively nontoxic at normal doses however long-term administration of high doses (2-6g daily) is associated with the development of severe peripheral neuropathies. Concerns exist about the possibility of neurotoxicity occurring. There have been reports of doses of 500mg daily having a toxic effect.
	4.5 Interactions Pyridoxine increases metabolism of levodopa. When levodopa is combined with carbidopa this effect is prevented. Isoniazid, cycloserine, pyrazinamide and penicillamine may antagonise the effects of pyridoxine and lead to a secondary deficiency. May decrease serum phenobarbitone. Patients taking oestrogens (eg, oral contraceptives) have higher vitamin B6 requirements.
	4.8 Undesirable effects Nausea, headache, paraesthesia, somnolence and low serum folic acid. Vitamin B6 is relatively nontoxic at normal doses however long-term administration of high doses (2-6g daily) is associated with the development of severe peripheral neuropathies. There have been reports of doses of 500mg daily having a toxic effect. Transient dependency symptoms may occur upon withdrawal of therapy at a dose of 200mg/day for over 1 month. The significance of this is not known however for patients on large doses for long period of time withdrawal of therapy should probably be gradual.
Cernevit injection (5.5mg)	**4.4 Warnings** Warnings for allergic reactions, vitamin toxicity (A, D, E), refeeding syndrome, pulmonary vascular precipitates, vitamin B12 deficiency, hepatic effects, effects on lab tests, and use in renal impairment. The renal impairment warning refers to pyridoxine: • Pyridoxine (Vitamin B6) hypervitaminosis and toxicity (peripheral neuropathy, involuntary movements) have been reported in patients on chronic haemodialysis receiving intravenous multivitamins containing 4mg pyridoxine administered three times a week.
	4.5 Interactions A number are listed, the pyridoxine relevant ones are: • Pyridoxine can reduce the effect of levodopa • Pyridoxine is light sensitive so need to protect the IV infusion mixture from light

	• Certain anticonvulsants (eg, phenytoin, carbamazepine, phenobarbital, valproate), Ethionamide, Pyridoxine antagonists (including cycloserine, hydralazine, isoniazid, penicillamine, phenelzine) and Theophylline can cause pyridoxine deficiency.
	4.8 Undesirable effects Vomiting, nausea, injection site reactions, vitamin A increased, liver enzymes increased, hypersensitivity reactions, dysgeusia, tachycardia, diarrhoea, pruritus, liver enzyme increased, pyrexia, generalised aching, infusion reactions
Pabrinex Syndrex Injection (10mg/mL)	**4.4 Warnings** Warnings for serious allergic reactions, and IV use only.
	4.5 Interactions Pyridoxine may interfere with the effects of concurrent levodopa therapy
	4.8 Undesirable effects Hypersensitivity, paraesthesia, hypotension, injection site reactions (all with unknown frequency)
Soluvit N Injection (4.9mg)	**4.4 Warnings** Warnings: monitor blood vitamin levels, biotin can interfere with blood tests
	4.5 Interactions B6 can reduce the effect of levodopa; folic acid may lower serum phenytoin.
	4.8 Undesirable effects Anaphylactic reactions

Source: Medsafe Data Sheet/CMI Search (accessed 20 February 2026).

Comments

Warnings and ADRs

The pyridoxine-containing data sheets contain different safety information. However, the products contain different quantities of pyridoxine, have different ingredients and different dose forms, which may partly explain the discrepancies.

Only the Pyridoxine Multichem and Cernevit data sheets have information about peripheral neuropathy. Hypersensitivity reactions and GI effects are more frequently listed.

Interactions

Most pyridoxine-containing data sheets contain the levodopa interaction. Although only the Pyridoxine Multichem data sheet refers to the mitigating effects of carbidopa. There are no levodopa-only approved products in NZ, all products contain carbidopa (with or without entacapone), beserazide or foscarbidopa. The oral levodopa + carbidopa products have an indication for patients with Parkinsonism who are taking vitamin preparations that contain pyridoxine hydrochloride. The levodopa + carbidopa intestinal gel and the foscarbidopa + levocarbidopa solution for infusion list vitamin B6 deficiency as a common ADR.

Only the Pyridoxine Multichem and Cernevit data sheets refer potential interactions with pyridoxine antagonists and anticonvulsants. Of these medicines, the data sheets for available pyridoxine antagonists and for phenobarbital contain information about effects on pyridoxine.

2.3.2.1 Other interactions

Stockley's Interaction Checker on the New Zealand Formulary also has interactions between pyridoxine interaction and altretamine, and pyridoxine and nitrofurantoin, as shown in Table 5.

Table 5: Pyridoxine interactions

Stockley's Interactions Alerts for: pyridoxine					
Medicines		**Explanation**	**Action**	**Severity**	**Evidence**
pyridoxine (systemic) and **altretamine** (systemic)		Pyridoxine reduced neurotoxicity associated with altretamine, but also reduced its effectiveness.	**Avoid:** The use of pyridoxine should probably be avoided in patients taking altretamine.	Moderate	Study
pyridoxine (systemic) and **levodopa** (systemic)		The effects of levodopa alone are reduced or abolished by the concurrent use of pyridoxine in doses as low as 5 to 10 mg daily. Loss of symptom control might start as soon as 24 hours after pyridoxine introduction.	**Information:** Addition of a dopa-decarboxylase inhibitor such as carbidopa (co-careldopa) or benserazide (co-beneldopa) prevents this interaction occurring. However, concurrent use in the absence of a dopa-decarboxylase inhibitor should be avoided.	Moderate	Extensive
pyridoxine (systemic) and **nitrofurantoin** (systemic)		Paraesthesias occurred in an elderly woman who had taken pyridoxine for several years and several courses of nitrofurantoin over a 10-year period.	**Information:** Information appears to be limited to this report, but bear it in mind in the event of unexpected toxicity.	Severe	Case
pyridoxine (systemic) and **phenobarbital** (systemic)		Daily doses of pyridoxine of 200 mg can cause reductions of 40 to 50% in phenobarbital concentrations in some patients.	**Monitor:** Concurrent use should be monitored if large doses of pyridoxine are used, being alert for the need to increase the phenobarbital dose. It seems unlikely that small doses (as in multivitamin preparations) will interact to any great extent.	Moderate	Case
pyridoxine (systemic) and **phenytoin** (systemic)		Daily doses of pyridoxine 80 to 400 mg can cause reductions of about 35% in phenytoin concentrations in some patients.	**Monitor:** Concurrent use should be monitored if large doses of pyridoxine are used, being alert for the need to increase the phenytoin dose. It seems unlikely that small doses (as in multivitamin preparations) will interact to any great extent.	Moderate	Case
pyridoxine (systemic) and **lumasiran** (systemic)		Pyridoxine does not have a clinically relevant effect on the pharmacokinetics or therapeutic effects of lumasiran.	**No action:** No action needed.	Nothing expected	Study

Source: New Zealand Formulary. 2026. *Stockley's Interaction Alerts*. URL: https://nzf.org.nz/nzf_1 (accessed 20 February 2026).

Comments

Altretamine: no approved products in NZ.

Nitrofurantoin: The pyridoxine-containing data sheets do not include this potential interaction. The nitrofurantoin data sheets have a warning for neuropathy, including peripheral neuropathy: 'Conditions such as …., vitamin B deficiency, ….. may enhance the occurrence of peripheral neuropathy.'

2.4 Dietary supplements: Products and uses

2.4.1 Products and uses

There is no database or register of vitamin B6-containing dietary supplements. Table 6 provides a few examples of different dietary supplements found on New Zealand websites, including the pyridoxine/vitamin B6 quantity, the advertised use and any warnings.

Table 6: Examples[a] pyridoxine-containing dietary supplements found on New Zealand websites

Product name[b] • **Pyridoxine/B6 quantity (per dose form and per day)**	**Use**	**Website warnings (relevant to pyridoxine)**
Vitamin B6 only		
Caruso's Vitamin B6 PMS Support • 121.55mg pyridoxine (100mg B6) • 100mg (1 tablet daily)	Support for premenstrual health and comfort: • Breast comfort • Mood balance • Fluid balance	• WARNING - This product contains pyridoxine which may be dangerous when used in large amounts or for a long time. • WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible.
Solgar Vitamin B6 100mg Vegetable Capsules • 100mg vitamin B6 (as pyridoxine HCl) • 100mg (1 capsule daily)	Supports: • normal homocysteine metabolism • normal energy metabolism and energy levels • normal nervous system function • normal physiological function • normal immune system function • regular hormonal function	Each vegetable capsules provides: Vitamin B6 (as pyridoxine HCl) 100 mg** **Long term intakes of this amount of vitamin B6 may lead to mild tingling and numbness.
Pyridoxine Vitamin B6 Tabs • 50mg vitamin B6 • Not specified online		
P-5-P • 25mg pyridoxal 5-phosphate • 25mg (1 capsule daily)	Supports: • Healthy kidney function • Cognitive health and brain function • Normal amino acid and protein metabolism	
Multi-ingredient products		
GO Healthy GO B Complex • 110mg (90.5mg Vitamin B6) • 110mg daily (1 capsule)	Maximum strength B vitamins to support energy production, healthy mood and nervous system function. • Supports energy production • Supports nervous system function • Nourishes the nervous system	Maximum daily dose of Vitamin B6 Recently, the Therapeutic Goods Administration (TGA) in Australia proposed a reduction in the maximum daily dose of Vitamin B6 from 100mg to 50mg, which is currently under review. No such changes have been proposed in New Zealand at this time. At all times, we will continue to ensure our products comply with the relevant maximum allowable daily dose set by applicable regulations. While Vitamin B6 is essential for health and has a long history of safe use, we understand that high doses or prolonged use may be linked to peripheral neuropathy in some individuals. We advise consumers to be mindful that taking multiple dietary supplements containing Vitamin B6 can contribute to their total daily Vitamin B6 intake exceeding recommended levels. Always read product labels, follow dosage instructions, and consult with a healthcare professional if you have any questions or concerns.

Product name[b] • **Pyridoxine/B6 quantity (per dose form and per day)**	**Use**	**Website warnings (relevant to pyridoxine)**
Clinician's B Complex Active • 61 mg pyridoxine HCl (Vit B6 50mg) • 61 mg daily (1 tablet)	• High-dose Vitamin B complex formulated to support at times of stress and fatigue. • For those who are looking to support healthy energy levels. • Support in times of stress, fatigue, exhaustion and tension.	
Healtheries Women's Multi • 45mg vitamin B6 • 45 mg daily (1 tablet)	Healtheries Women's Multi is a high-potency One-a-Day multivitamin and mineral supplement to help busy New Zealand women "top up" the nutrients they most need. This formula contains high potency B vitamins and Siberian Ginseng to aid with energy - helping to maintain vitality to face whatever life throws your way. Ideal if you're busy, tired, stressed or overworked.	
Blackmores Bio Magnesium • 50mg pyridoxine HCl (vitamin B6) • 50 mg daily (1 tablet) – or as prescribed	• Reduces muscle tension & stiffness when dietary intake is inadequate • Supports bone health • Supports heart health • Supports muscle health • Supports muscle function • Supports nervous system health • Supports general health and wellbeing	• **WARNING** - This product contains Pyridoxine hydrochloride which may be dangerous when used in large amounts or for a long time • **WARNING** - Stop taking the medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6] • Pyridoxine-induced peripheral neuropathy is most commonly reported with doses of 1 g or more daily, taken for 2 months to 3 years • If symptoms persist, see your healthcare professional.
Swisse Ultivite Men's Multivitamin • 24.68 mg vitamin B6 (pyridoxine from pyridoxine HCl) • 24.68 mg daily (1 tablet) – or as directed by a healthcare professional	• Supports immune health and muscle function • Supports energy production and brain function	• Stop taking this product if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].
Centrum for Women 50+ • 9.7mg pyridoxine hydrochloride (vitamin B6) • Not stated online	• Cognition support • Support bone health • Immunity support • Support post-menopausal health	

a. Not a comprehensive list.

b. Where possible, the hyperlinked product name is to the NZ manufacturer's website. Where there is no NZ manufacturer website, the hyperlinks are to NZ retailers.

Comments

The pyridoxine quantity per dose form varies considerably.

All products in the table contain significantly more pyridoxine than the recommended dietary intake of 1.3mg, and some have more than the recommended upper limit of 50mg.

The online ingredients lists are inconsistent with labelling. Some provide the pyridoxine HCl quantity and provide a B6 equivalent, some refer to both (but have the same quantity) and others refer to one or the other.

One product only refers to magnesium in the product name but contains 50mg of pyridoxine as an active ingredient.

A few products have warnings about peripheral neuropathy, likely due to labelling requirements in Australia as discussed in section 2.6 below.

2.4.1.1 Bariatric surgery

Following bariatric surgery, patients are at risk of getting nutrient deficiencies and need to take a multivitamin tablet every day for life [4].

Health New Zealand has information about nutrition supplements after weight loss surgery, with a list of supplements that provide good nutrient levels [5]. Table 7 shows these supplements, and their pyridoxine levels, and Table 8 provides the daily nutrition supplement options by surgery type and corresponding daily dose of pyridoxine. These products are not Pharmac funded.

Table 7: Multivitamin supplement options for bariatric surgery patients[a] and their pyridoxine levels

Product Name	Pyridoxine content[b]
BN Caps	790mcg Pyridoxal-5-phosphate (650mcg vitamin B6)
BN Chews	790mcg Pyridoxal-5-phosphate (650mcg vitamin B6)
BariLife Just One	4mg Vitamin B6 (as pyridoxine HCl)
BariLife Complete powder	4mg Vitamin B6 (as pyridoxine HCl) per 7.8mg scoop
TRIC Multivitamin + iron 24 mg	4mg Pyridoxal-5-Phosphate (Vit B6)
TRIC Multivitamin (no iron)	2mg Pyridoxal-5-Phosphate (Vit B6)
My New Tum	2.5mg Vitamin B6 (pyridoxine)
Centrum Women's	6mg Pyridoxine hydrochloride (vitamin B6)

a. Health New Zealand. 2023. *Nutrition supplements after weight loss surgery* updated 7 January 2026. URL: https://info.health.nz/health-topics/tests-and-treatments/surgery/bariatric-weight-loss-surgery/nutrition-supplements-after-weight-loss-surgery (accessed 23 February 2026).

b. As per the website link.

Table 8: Daily nutrition supplement options[a] by surgery type, and corresponding daily pyridoxine dose

Surgery type	Product and recommended daily dose (patients choose 1 option)	Daily pyridoxine dose[b]
Sleeve gastrectomy (gastric sleeve) or Roux-en-Y gastric bypass, or mini bypass (if bypassed length <150cm)	2 x BN Caps	1.58mg Pyridoxal-5-phosphate (1.3mg vitamin B6)
	2 x BN Chews	1.58mg Pyridoxal-5-phosphate (1.3mg vitamin B6)
	1 x BariLife Just One	4mg Vitamin B6 (as pyridoxine HCl)
	6 x BariLife Complete	24mg Vitamin B6 (as pyridoxine HCl)
	1 x TRIC Multivitamin + iron 24 mg	4mg Pyridoxal-5-Phosphate (Vit B6)
	1 x TRIC Multivitamin (no iron)	2mg Pyridoxal-5-Phosphate (Vit B6)
	2 x My New Tum	5mg Vitamin B6 (pyridoxine)
	2 x Centrum Women's	12mg Pyridoxine hydrochloride (vitamin B6)
Duodenal switch (DS) or single anastomosis duodenal switch (SADI-S), or mini bypass (if bypassed length >150cm)	8 x BariLife Complete	32mg Vitamin B6 (as pyridoxine HCl)
	1½ x BariLife Just One	6mg Vitamin B6 (as pyridoxine HCl)

a. Health New Zealand. 2023. *Nutrition supplements after weight loss surgery* updated 7 January 2026. URL: https://info.health.nz/health-topics/tests-and-treatments/surgery/bariatric-weight-loss-surgery/nutrition-supplements-after-weight-loss-surgery (accessed 23 February 2026).

b. As per the website link.

2.5 Funding

Pharmac funds pyridoxine-only products and multi-ingredient products in the community and in hospitals, as shown in Table 9. Only two of the funded products are approved medicines, six are section 29 medicines and the rest are dietary supplements or foods. There is also a pyridoxal-5-phosphate product (the metabolically active, "tissue-ready" coenzyme form of vitamin B6) that is funded in hospitals.

Note that Pharmac also funds a number of special foods, some of which contain small amounts of pyridoxine, but these are excluded from the table.

Table 9: Pyridoxine funding (excluding foods) – Community and Hospital

Brand or generic manufacturer	Pyridoxine	Community	Hospital	Classification (for medicines only)
Vitamins: Vitamin B				
Bplex Vitamin B complex	2mg	500 tablets	1,000 tablets	
Vitamin B6 25 (Evara)	25mg	No more than 100mg per dose Only on prescription 90 tablets		
Pyridoxine Multichem	50mg	No more than 100mg per dose Only on prescription 500 tablets	500 tablets	General sale medicine
Pyridoxine hydrochloride (Baxter)	100mg/mL			Prescription medicine – section 29
Pyridoxine hydrochloride (Mylan)	3g/30mL			Prescription medicine – section 29
Vitamins: Multivitamin preparations				
Clinicians Renal Vit	8.2mg	Special Authority for patients with chronic kidney disease 30 capsules	Restricted to patients with chronic kidney disease	
Paediatric Seravit powder	3.6mg/100g	Special Authority for patients with inborn errors of metabolism 200g powder	Restricted to patients with inborn errors of metabolism 200g powder	
Vitabdeck[a]	1.9mg	Special Authority for patients with cystic fibrosis with pancreatic insufficiency, infants or children with liver disease or short gut syndrome, patients with severe malabsorption syndrome 60 capsules	Restricted to patients with cystic fibrosis with pancreatic insufficiency, infants or children with liver disease or short gut syndrome, patients with severe malabsorption syndrome	
Clinicians Multivitamin & Mineral Boost capsules	5mg		Restricted to patients admitted to hospital with burns	
Pabrinex IV (Max Health)[b]	50mg/5mL ampoule		Restricted to patients with inborn errors of metabolism	Prescription medicine
Pabrinex IV (Kyowa Kirin)[b]	50mg/5mL ampoule		Restricted to patients with inborn errors of metabolism	Prescription medicine – section 29

Brand or generic manufacturer	Pyridoxine	Community	Hospital	Classification (for medicines only)
Pabrinex IV (Archimedes Pharma)[b]	50mg/5mL ampoule		Restricted to patients with inborn errors of metabolism	Prescription medicine – section 29
Pabrinex IV (Archimedes Pharma)[b]	100mg/10mL ampoule		Restricted to patients with inborn errors of metabolism	Prescription medicine – section 29
Pabrinex Intramuscular[b]	50mg/5mL ampoule		Restricted to patients with inborn errors of metabolism	Prescription medicine – section 29
Metabolic disorder agents				
Pyridoxal-5-Phosphate - Any brand	50mg		Restricted: prescribed by or recommended by neurologist, metabolic physician or metabolic disorders dietitian	

a. Vitabdeck is referred to as "fat soluble vitamins A, D, E, K" in the Community Schedule, but it contains pyridoxine. Vitabdeck is the example generic product in the Hospital Medicines List, but it is not a contracted product.

b. Pabrinex IV is the example generic product given in the HML, but it is not a contracted product, and any brand may be used. Max Health is an approved medicine, but the other brands (obtained from the NZULM) are not.

Sources:

PHARMAC. 2026. *Pharmaceutical Schedule* Vol 33, February 2026. URL: https://schedule.pharmac.govt.nz/2026/02/01/Schedule.pdf (accessed 9 February 2026).

PHARMAC. 2026. *Hospital Medicines List* Vol 14, February 2026. URL: https://schedule.pharmac.govt.nz/2026/02/01/HML.pdf (accessed 9 February 2026).

New Zealand Formulary (NZF). 2026. *New Zealand Universal List of Medicines (NZULM) Search*. URL: https://nzf.org.nz/nzulm (accessed 20 February 2026).

2.5.1 Usage data

Table 10 shows that community dispensings for the funded products have generally increased from 2020 to 2024. However, as pyridoxine is also an ingredient in other medicines and dietary supplements, and is funded in hospitals, community dispensing data will significantly underestimate true use.

Table 10: Community dispensing data, pyridoxine-containing products, 2020 to 2024

Vitamin B complex[a]				
	Initial		Dispensings	
Year	NumDisps	NumPpl	NumDisps	NumPpl
2020	37665	14635	85870	14732
2021	41874	15825	85646	15948
2022	47231	17687	93471	17840
2023	52431	19868	100684	20012
2024	58650	21721	111787	21877
Pyridoxine hydrochloride 25mg tablets[b]				
	Initial		Dispensings	
Year	NumDisps	NumPpl	NumDisps	NumPpl
2020	8856	5516	13985	5558
2021	8820	5907	12481	5991
2022	11304	7469	15811	7536
2023	11775	8003	15994	8074
2024	13740	9256	18491	9309
Pyridoxine hydrochloride 50mg tablets[c]				
	Initial		Dispensings	
Year	NumDisps	NumPpl	NumDisps	NumPpl
2020	14826	7545	28084	7614
2021	16211	8491	28370	8615
2022	14248	7172	32617	7405
2023	14514	7271	27664	7507
2024	15405	7784	25162	7847
Multivitamin renal capsules[d]				
	Initial		Dispensings	
Year	NumDisps	NumPpl	NumDisps	NumPpl
2020	12063	3221	36596	3270
2021	12922	3428	37159	3482
2022	13385	3664	38050	3711
2023	14182	3767	38859	3814
2024	15076	3892	42308	3941

continues

Multivitamin powder[e]				
	Initial		Dispensings	
Year	NumDisps	NumPpl	NumDisps	NumPpl
2020	44	15	59	15
2021	42	19	59	19
2022	54	25	81	25
2023	47	20	69	20
2024	29	15	44	15
Vitamins – Cap (fat soluble vitamins, A, D, E, K)[f]				
	Initial		Dispensings	
Year	NumDisps	NumPpl	NumDisps	NumPpl
2020	1729	600	3063	606
2021	1834	654	3085	656
2022	1986	715	3272	718
2023	2203	834	3568	840
2024	2543	927	4341	935

a. Bplex is the currently funded Vitamin B complex product.

b. Vitamin B6 25 (Evara) is the currently funded Pyridoxine hydrochloride 25mg product.

c. Pyridoxine Multichem is the currently funded Pyridoxine hydrochloride 50mg product.

d. Clinicians Renal Vit is the currently funded Multivitamin renal capsules product.

e. Paediatric Seravit is the currently funded Multivitamin powder.

f. Vitabdeck is the currently funded Vitamins – cap (fat soluble vitamins, A, D, E, K) product.

NumDisps: Number of times a pharmaceutical product is dispensed to the named person from a pharmacy. When 'Initial dispensings' is chosen as a type of measure, only the initial dispensing or if the product is dispensed all at once is counted (ie, excludes repeat dispensings).

NumPpl: Number of people who received at least one dispensing of the pharmaceutical product as a named person from the pharmacy during the year. When 'Initial dispensings' is chosen as a type of type of measure, the NumPpl count excludes people who only received repeat dispensings of the prescription item during the year

Source: Health New Zealand. 2025. Pharmaceutical Data web tool version 14 August 2025 (data extracted from the Pharmaceutical Collection on 4 June 2025). URL: https://tewhatuora.shinyapps.io/pharmaceutical-data-web-tool/ (accessed 20 February 2026).

2.6 Regulatory action in Australia

2.6.1 Regulation of vitamins

In Australia, the Therapeutic Goods Administration (TGA) regulates all vitamins for safety and quality [6]. Depending on the vitamin type and the dose, vitamins are regulated either as registered medicines (prescription medicines or registered complementary medicines), or as listed medicines (listed or assessed listed medicines).

Listed medicines are low-risk, non-prescription products and must be included in the Australian Register of Therapeutic Goods (ARTG) before supply. Listed medicines can only contain pre-approved low-risk ingredients and only make pre-approved low-level health claims. The TGA does not assess listed medicines before supply. Sponsors must self-certify that the product complies with all the safety, quality and efficacy requirements that apply to their medicine. Most vitamins are listed medicines [7].

Assessed listed medicines are slightly higher risk than listed medicines. They require pre-market assessment by the TGA for evidence of efficacy for all indications before listing in the ARTG [8].

Registered complementary medicines are considered to be of relatively higher risk than listed medicines, based on their ingredients or the indications made for the medicine. Registered medicines are fully evaluated by the TGA for quality, safety and efficacy prior to being accepted on the ARTG [9].

2.6.2 Regulatory action

Following an increase in reports of peripheral neuropathy (PN) associated with pyridoxine use in Australia, the Therapeutic Goods Administration (TGA) lowered the permitted daily dose in listed pyridoxine-containing medicines and strengthened labelling requirements [10-12].

Since March 2022, medicines containing daily doses of vitamin B6 over 10mg or equivalent have been required to a warning statement about the risk of peripheral neuropathy. This label warning was previously only required for daily doses of vitamin B6 over 50 mg.

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

At the same time, the TGA also lowered the maximum daily dose in listed medicines to 100mg for adults and lower amounts for children:

- 15 mg of pyridoxine for children aged between 1 and 3 years (inclusive)
- 20 mg of pyridoxine for children aged between 4 and 8 years (inclusive)
- 30 mg of pyridoxine for children aged between 9 and 13 years (inclusive)
- 40 mg of pyridoxine for individuals aged 14 and 18 years (inclusive)
- 100 mg of pyridoxine for individuals aged 19 years and older.

Following continued reports of PN, in November 2024 the TGA consulted on proposed changes to the Poisons Standard to change the scheduling of pyridoxine, pyridoxal or pyridoxamine.

The final decision was published in November 2025. From 1 June 2027, medicines containing more than 50mg but less than 200mg per recommended daily dose of vitamin B6 will be reclassified as Pharmacist Only Medicines (Schedule 3) – as shown in Table 11. Medicines with more than 200mg are already classified as Prescription Only Medicines (Schedule 4) and products with low doses of vitamin B6 (<50mg) will continue to be available for general sale (listed medicines).

At least 125 medicines available in Australia will be affected by this scheduling change, that is, they contain more than 50mg but less than 200mg vitamin B6 per maximum recommended daily dose.

Table 11: Scheduling of pyridoxine in Australia

Current – until 1 June 2027	New – from 1 June 2027
Schedule 4 (Prescription) PYRIDOXINE, PYRIDOXAL OR PYRIDOXAMINE for human therapeutic use **except**: (a) in oral preparations containing 200 mg or less but more than 50 mg of pyridoxine, pyridoxal or pyridoxamine per recommended daily dose when compliant with the requirements of the required advisory statements for medicine labels; or (b) in oral preparations containing 50 mg or less of pyridoxine, pyridoxal or pyridoxamine per recommended daily dose.	**Schedule 4 (Prescription)** PYRIDOXINE, PYRIDOXAL OR PYRIDOXAMINE for human therapeutic use **except**: (a) when included in Schedule 3; or (b) in oral preparations containing 50 mg or less of pyridoxine, pyridoxal or pyridoxamine per recommended daily dose. **Schedule 3 (Pharmacist only)** PYRIDOXINE, PYRIDOXAL OR PYRIDOXAMINE for human therapeutic use in oral preparations containing 200 mg or less but more than 50 mg of pyridoxine, pyridoxal or pyridoxamine per recommended daily dose.

Source: Therapeutic Goods Administration. 2025. *Notice of final decision to amend (or not amend) the current Poisons Standard in relation to pyridoxine, pyridoxal or pyridoxamine (vitamin B6)* 25 November 2025. URL: https://www.tga.gov.au/sites/default/files/2025-11/notice-final-decision-to-amend-current-poisons-standard-pyridoxine-pyridoxa-pyridoxamine-vitamin-b6.pdf (accessed 26 November 2025).

3 NEW ZEALAND ADR DATA

3.1 About the data

[redacted] New Zealand ADR data from April 1988 (when the first report was received) to 31 December 2025. The data was extracted from the New Zealand Pharmacovigilance Database on 3 October 2025 and updated on 9 February 2026.

The extracted data includes reports where a pyridoxine/vitamin B6-containing product was reported and coded as the suspect medicine/dietary supplement. To capture all potential reports, the New Zealand Pharmacovigilance Database was also searched using the WHO's Anatomic Therapeutic Chemical (ATC) level 2 classification 'Vitamins' (ATC: A11).

Case narratives for both data sets were reviewed:

- if the case narrative stated that pyridoxine/vitamin B6 was a suspect ingredient (eg, there was an ingredients list provided with the report), then that report was added to the extract
- if the case narrative provided an ingredients list and pyridoxine/B6 was not included in that list, then the report was removed from the extract.

[redacted]

3.1.1 Limitations

The usual limitations for spontaneously reported ADR data apply, including the following [13].

- The likelihood of experiencing an adverse reaction cannot be estimated from this data as there is no information on how many people have taken the medicine or dietary supplement and the extent of under-reporting is not known.
- Anyone living in New Zealand who thinks they may have experienced an adverse reaction can report it. This does not necessarily mean that the medicine caused the reaction.
- The number of reports for a medicine (or dietary supplement) can be influenced by how many patients are taking the medicine, media attention, the nature of the reactions, and other factors which vary over time.
- The quality of the information in the database is limited by the quality of the original report.
- The information contained in the database may change over time due to quality control procedures and/or receipt of further information.
- Reactions may also be caused by other ingredients in the medicine or dietary supplement.

Additional limitations relevant to this data set include the following.

<u>Reporting</u>

- People may not think to report reactions to a dietary supplement or food.
- The reporter may have only reported the suspected product and not any other medicines or dietary supplements they were taking.
- The reporter may have given the incorrect dietary supplement name and/or ingredient.

Products

- Most dietary supplements contain multiple ingredients, so it's difficult to determine which (if any) may be causing the reaction.
- Dietary supplement ingredients (actives and quantities) change over time. A product that is marketed now may contain different ingredients from when the reaction was reported (even if the product name is the same).

[redacted]

3.2 Reports, product types, demographics and indications

For the period April 1988 (when the first report was received) to 31 December 2025, there were 145 reports where the suspect product contained pyridoxine. The suspect product was a dietary supplement in 120 reports and a medicine in 25 reports (Table 12).

Table 12: Number of pyridoxine reports by suspect product type (dietary supplement or medicine)

Report type [redacted]	No.
Dietary supplement (or food)	**120**
Suspect product is a dietary supplement (or food) that contains pyridoxine. There are no concomitant or co-suspect non-pyridoxine products in the report.	60
Suspect product is a dietary supplement (or food) that contains pyridoxine, and there are also co-suspect or concomitant non-pyridoxine products in the report.	60
Medicine	**25**
Suspect product is a medicine that contains pyridoxine. There are no concomitant or co-suspect products in the report.	13
Suspect product is a medicine that contains pyridoxine, and there are also co-suspect or concomitant non-pyridoxine products in the report.	12
Total	**145**

[redacted]

Thirty of the 145 reports were reported in 2025. Some of these may have been stimulated by publicity around regulatory changes in Australia and the June 2025 Prescriber Update article Vitamin B6 (pyridoxine) and peripheral neuropathy.

3.2.1 Product types

3.2.1.1 Dietary supplements

- Half of the dietary supplement reports (60/120) reported only a single suspect product with no concomitants or co-suspects. However, in most cases, the suspect dietary supplement has multiple active ingredients, including pyridoxine.
- In 33 reports, the person was taking more than one dietary supplement. In 9 reports, there were 2 co-suspect pyridoxine-containing dietary supplements (ie, the person was taking 2 different supplements, each containing pyridoxine).
- A wide range of dietary supplement manufacturers were reported. [redacted]
- Pyridoxine dose was rarely reported:

[redacted]

  - Daily dose can be estimated for a number of reports based on the ingredients list provided with the report or the reported product name and an internet search for that product and ranged from 1.3mg to 280mg per day.

3.2.1.2 Medicines

- About half of the medicine reports (13/25) reported a single suspect product.

[redacted]

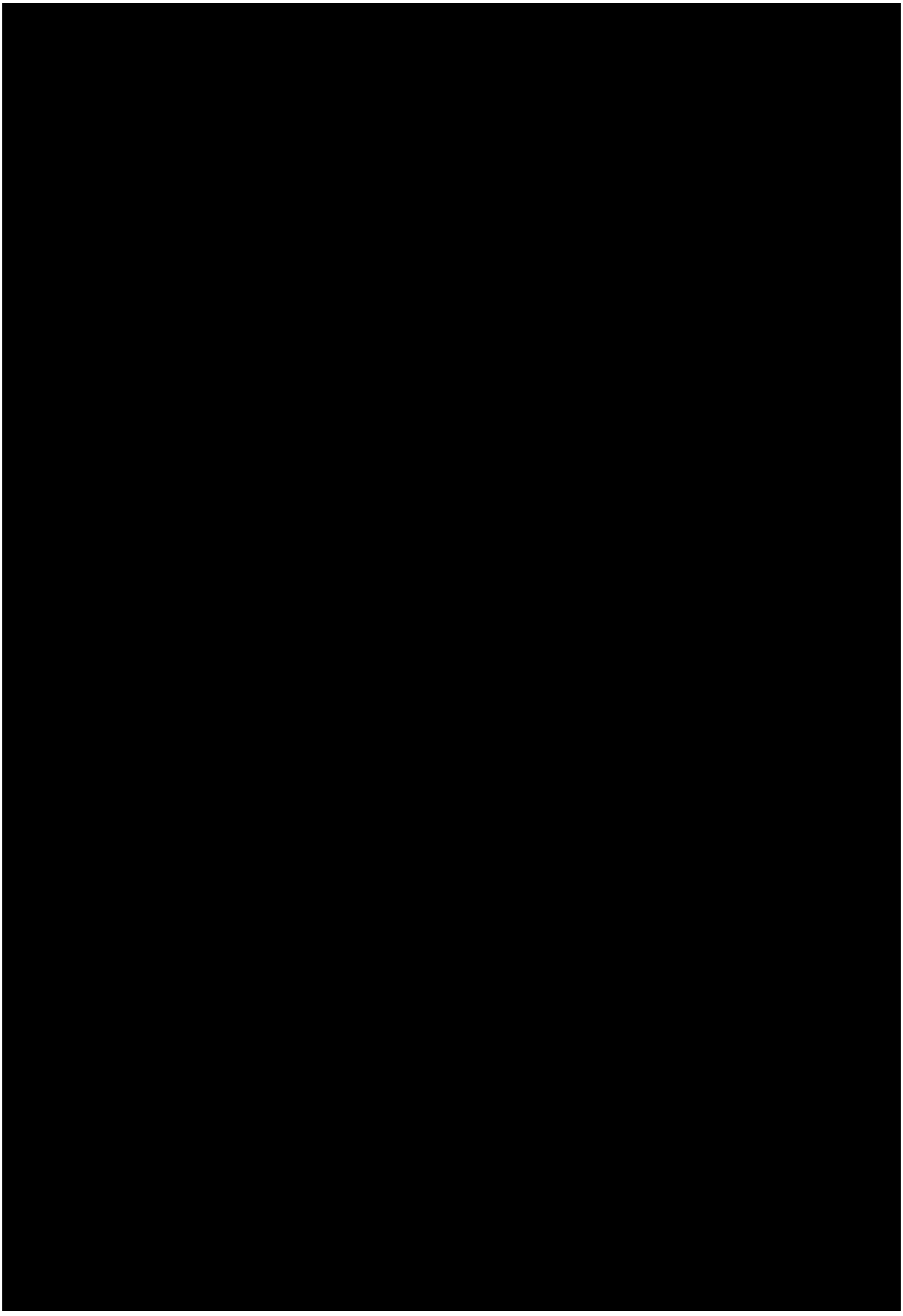
- Pyridoxine dose:
  - [redacted]
  - daily dose can be estimated for most cases based on the reported medicine name and/or case narrative and ranged from 1.9mg pyridoxine to 150mg pyridoxine per day.

3.2.2 Demographics

[redacted].

- Age was reported in 120 reports, with a mean age of 48 years (median 49 years; range 0 to 81 years). Most reports were in those aged 18 to 44 years (n=48).
- Sex was reported in 133 reports. Most reports were in females (n=88), with 45 reports in males.
- By sex and age, females aged 18-44 years were the subject of most reports (n=33), followed by females aged 45 to 64 years (n=26).
- Ethnicity was reported in 79 reports. Most reports described people of European or Other ethnicity (n=69).
- Most reports were from consumers (n=75), followed by GPs (n=24).

[redacted]



[redacted]

3.3 ADRs

3.3.1 Reported reactions

[redacted]

There were 308 reactions reported in the 145 cases. Table 15 lists the reactions that were reported 2 or more times. Vitamin B6 increased was the most frequently reported reaction (n=17), followed by diarrhoea (11) and nausea (11). Most of these were reported in association with a dietary supplement.

As shown in Table 16, reactions were reported in 22 different System Organ Classes (SOCs). The Gastrointestinal disorders SOC had the most reported reactions (51), followed by Nervous system disorders (49) and Skin and subcutaneous disorders (36).

Table 15: Most frequently reported reactions (≥2 reports), by product type

Reaction*	All products	Dietary supplements	Medicines
Vitamin B6 increased	17	17	0
Diarrhoea	11	7	4
Nausea	11	7	4
Headache	8	6	2
Pruritus	8	7	1
Vomiting	8	5	3
Rash	6	6	0
Hepatic function abnormal	5	4	1
Vitamin toxicity specified	5	5	0
Abdominal pain	4	3	1
Angioedema	4	3	1
Cramp abdominal	4	1	3
Dizziness	4	4	0
Fatigue	4	3	1
Hypertension	4	4	0
Anaphylactic reaction	3	3	0
Anxiety	3	3	0
Arthralgia	3	3	0
Bronchospasm	3	2	1
Chest pain	3	3	0
Constipation	3	3	0
Face oedema	3	2	1
Flushing	3	1	2
Hepatic enzymes increased	3	3	0
Lethargy	3	3	0
Malaise	3	2	1
Myalgia	3	3	0
Oedema peripheral	3	2	1
Peripheral neuropathy	3	3	0
Urticaria	3	2	0
Abortion	2	0	2
Decreased appetite	2	2	0
Drug exposure during pregnancy	2	0	2
Drug interaction	2	2	0
Epistaxis	2	1	1
Euphoria	2	1	1
Foetal disorder	2	0	1
Hepatitis	2	2	0
Hypervitaminosis B6	2	1	1

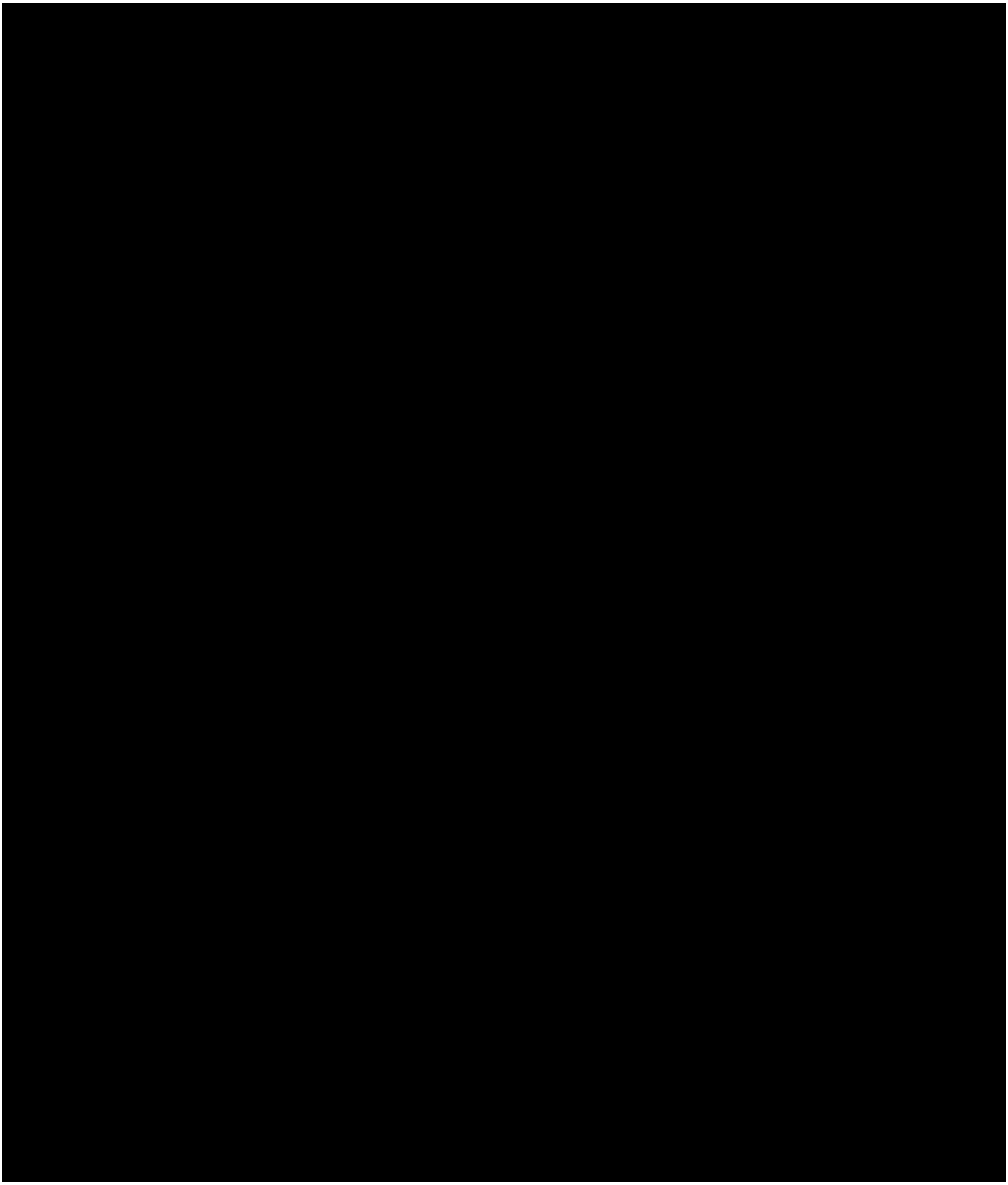
Reaction*	All products	Dietary supplements	Medicines
Mental impairment NOS	2	2	0
Migraine	2	1	1
Neuropathy	2	2	0
Peripheral neuropathy aggravated	2	2	0
Rash maculo-papular	2	2	0
Sleep disturbed	2	2	0
Tachycardia	2	2	0
Thirst	2	2	0
Tiredness	2	0	2
Toxic epidermal necrolysis	2	2	0
Vitamin toxicity	2	2	0

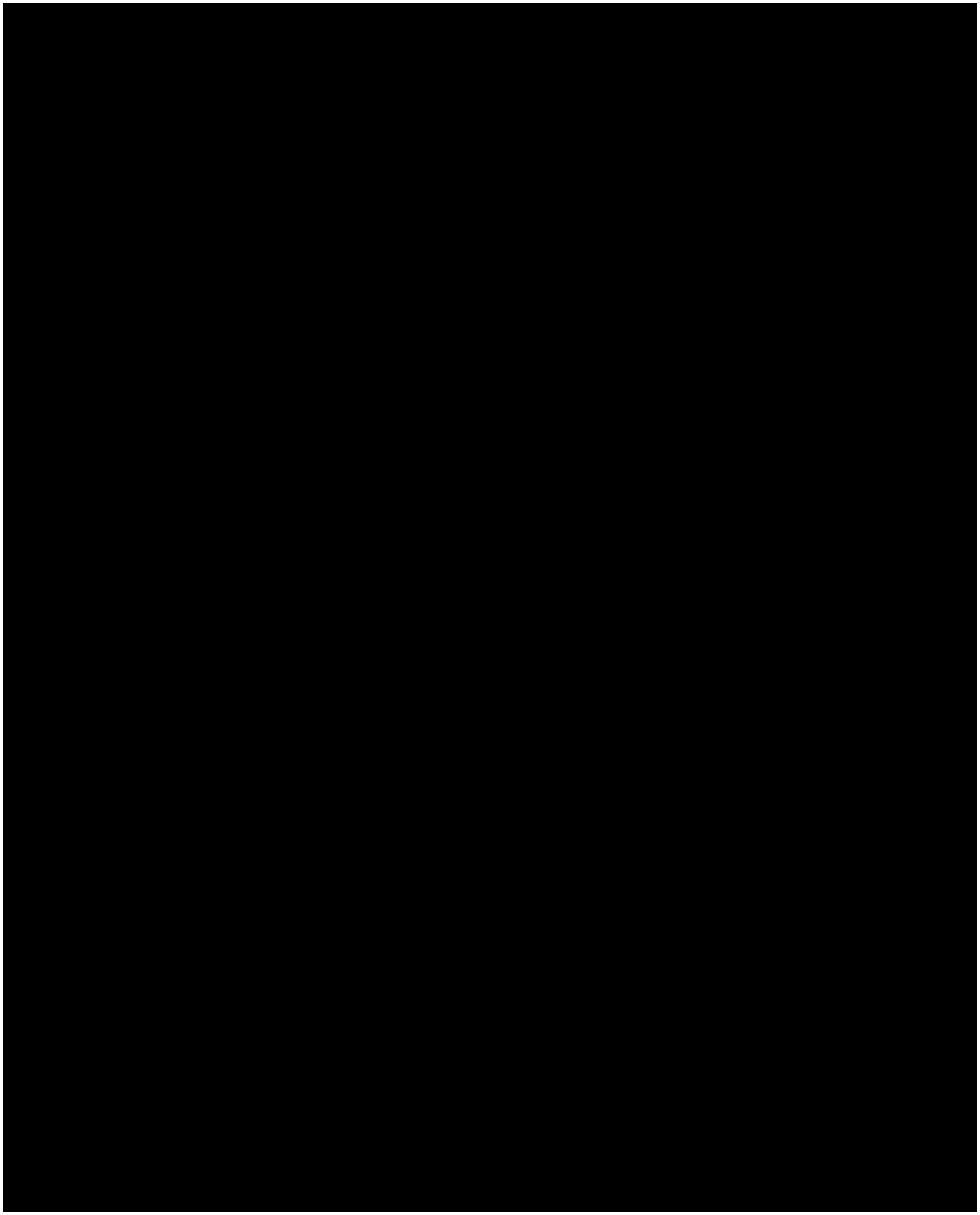
* [redacted] Coded at the MedDRA Preferred term (PT) or Lowest level term (LLT) level.

Table 16: Reactions per System Organ Class (SOC)

SOC	All products No.	Dietary Supplements No.	Medicines No.
Gastrointestinal disorders	51	35	16
Nervous system disorders	49	42	7
Skin and subcutaneous tissue disorders	36	31	5
General disorders and administration site conditions	34	27	7
Investigations	32	31	1
Metabolism and nutrition disorders	17	16	1
Psychiatric disorders	16	15	1
Musculoskeletal and connective tissue disorders	13	13	0
Vascular disorders	12	8	4
Hepatobiliary disorders	8	6	2
Respiratory, thoracic and mediastinal disorders	8	3	5
Injury, poisoning and procedural complications	6	2	4
Immune system disorders	4	3	1
Pregnancy, puerperium and perinatal conditions	4	0	4
Renal and urinary disorders	4	3	1
Cardiac disorders	3	3	0
Congenital, familial and genetic disorders	3	0	3
Eye disorders	2	2	0
Infections and infestations	2	2	0
Reproductive system and breast disorders	2	0	2
Product issues	1	1	0
Surgical and medical procedures	1	0	1

* System Organ Class – the MedDRA top level, which groups terms by aetiology, manifestation site or purpose. Some PTs/LLTs belong to more than 1 SOC, so only the primary SOC was used.





[redacted]

[redacted]

3.4 Peripheral neuropathy (PN)

There is a Standardised MedDRA Query (SMQ) for peripheral neuropathy. An SMQ is a validated, standard set of MedDRA terms that has undergone extensive review, testing, analysis and expert discussion [14].

The Peripheral Neuropathy SMQ definition is [15]:

- Impairment of the peripheral motor, sensory and autonomic nervous system
- Diagnosis is on clinical grounds, supplemented by electrophysiological investigation
- At least one of the following must be present:
  - Muscular weakness with diminished tone, or flaccid paralysis (diminished tendon reflexes and wasting)
  - Sensory disturbances, including pain
  - Impairment of autonomic function.

[redacted]

3.4.2 Products

- Of the 11 cases, 10 were associated with dietary supplements and 1 with a medicine.
  - [redacted]

3.4.6 Reactions

In the 11 medically confirmed PN cases, there were 14 different reactions reported (24 reactions in total) from 4 different SOCs, as shown in Table 18. The most frequently reported reactions were vitamin B6 increased (6), peripheral neuropathy (3), neuropathy (2), peripheral neuropathy aggravated (2) and mental impairment (2).

Table 18: Medically confirmed PN cases – reported reactions[a] by SOC[b]

SOC	No.
General disorders and administration site conditions	**1**
Energy decreased	1
Investigations	**7**
Vitamin B6 increased	6
Drug level increased	1
Metabolism and nutrition disorders	**1**
Vitamin toxicity specified	1
Nervous system disorders	**15**
Peripheral neuropathy	3
Mental impairment NOS	2
Neuropathy	2
Peripheral neuropathy aggravated	2
Balance impaired NOS	1
Hand tingling	1
Headache	1
Neuropathy peripheral	1
Paraesthesia distal	1
Small fibre neuropathy	1

a. [redacted] Coded at the MedDRA Preferred term (PT) or Lowest level term (LLT) level.

b. System Organ Class – the MedDRA top level, which groups terms by aetiology, manifestation site or purpose. Some PTs/LLTs belong to more than 1 SOC, so only the primary SOC was used.

[redacted]

3.5 Increased vitamin B6 levels

24 cases reported increased vitamin B6 levels [redacted]

- The reported terms were vitamin B6 increased (17), vitamin toxicity specified (5,) hypervitaminosis B6 (2), vitamin toxicity (2) and drug level increased (1).
- 23/24 cases were associated with dietary supplements, and 1 with a medicine.
  - [redacted]

[redacted]

[redacted]

4 DISCUSSION AND CONCLUSIONS

The recommended dietary intake (RDI) for vitamin B6 (as pyridoxine) is only 1.3mg/day for adults, which increases slightly in older age. The RDI is slightly higher again in pregnancy and lactation. The current recommended upper limit for adults is 50mg/day (this upper limit will be reviewed in 2026). Most people can get sufficient vitamin B6 from food sources and clinical deficiency is rare.

Vitamin B6/pyridoxine is regulated as a medicine and as a dietary supplement in New Zealand. The Medicines Regulations 1984 classify pyridoxal, pyridoxamine and pyridoxine as prescription when in medicines with >200mg per recommended daily dose and as general sale when in medicines ≤200mg per recommended daily dose. A recommended daily dose of 200mg is more than 15,000% of the recommended dietary intake.

There is no maximum upper limit for vitamin B6/pyridoxine defined in the Dietary Supplements Regulations.

There are only a few approved pyridoxine-containing medicines available in New Zealand. Of these, the pyridoxine content ranges from 2.54mg (1.9mg vitamin B6) to 50 mg per dose form. Most pyridoxine-containing products are available as dietary supplements, and the pyridoxine content varies considerably – from less than 1mg to more than 100mg per dose form.

For dietary supplements, the online ingredients lists are inconsistent with labelling. Some provide the pyridoxine HCl quantity and provide a B6 equivalent, some refer to both (but have the same quantity) and others refer to one or the other. Some products contain high levels of pyridoxine (50mg), but the product name only refers to magnesium.

Peripheral neuropathy is the main safety concern associated with taking pyridoxine. According to the data sheets, this is seen with long-term administration of high doses (2–6g daily), but doses of 500mg daily have been reported to have toxic effects. Hypersensitivity reactions and GI effects are also known safety concerns for approved medicines. A few dietary supplement products have warnings for peripheral neuropathy.

Following an increase in reports of peripheral neuropathy associated with pyridoxine use in Australia, the Therapeutic Goods Administration (TGA) lowered the permitted daily dose in listed pyridoxine-containing medicines and strengthened labelling requirements. All listed medicines (general sales) containing more than 10mg of vitamin B6 or equivalent are required to have a warning about peripheral neuropathy. From 1 June 2027, products containing more than 50mg of pyridoxine but less than 200mg will be rescheduled as pharmacist only medicines. Those containing more than 200mg will continue to be prescription medicines and those containing less than 50mg will continue to be available as general sales.

From April 1988 to 31 December 2025, there were 145 adverse reaction cases reported in New Zealand where the suspect product contained pyridoxine. The suspect product was a dietary supplement in 120 reports and a medicine in 25 reports. The estimated daily pyridoxine dose in these reports ranged from 1.3mg to 280mg.

Vitamin B6 increased was the most frequently reported reaction, followed by diarrhoea and nausea. Most reports were not serious, and most people had recovered or were recovering from the ADR at the time of the report.

[redacted]

There were 11 medically confirmed reports of peripheral neuropathy, 10 of which were associated with a dietary supplement. [redacted]

There were 24 reports of increased vitamin B6 levels, [redacted]

There were multiple case reports where the person was taking more than one pyridoxine-containing product. It may be difficult for consumers to estimate their pyridoxine intake because many dietary supplements contain pyridoxine, and it is labelled in different ways in these products. Also, consumers may not understand that combining multiple pyridoxine-containing products can lead to high levels in the body.

[redacted]

5 ADVICE SOUGHT

The Committee is asked to advise:

- Are there any safety concerns with pyridoxine-containing products?
  - If yes, is any regulatory action required?
- Is there a risk of serious side effects from pyridoxine-containing products available at doses without a prescription?
  - If yes, is any regulatory action required?

[redacted]

7 REFERENCES

1. Muhamad R, Akrivaki A, Papagiannopoulou G, et al. 2023. The role of vitamin B6 in peripheral neuropathy: a systematic review. *Nutrients* 15(13): 2823.
2. National Health and Medical Research Council and Australian Government Department of Health and Ageing and New Zealand Ministry of Health. 2006. *Nutrient Reference Values for Australia and New Zealand* URL: https://www.nhmrc.gov.au/sites/default/files/images/nutrient-refererence-dietary-intakes.pdf (accessed 2 May 2025).
3. New Zealand Formulary (NZF). 2026. *NZF v164: Pyridoxine hydrochloride* 1 February 2026. URL: https://nzf.org.nz/nzf_5355 (accessed 11 February 2026).
4. Health New Zealand. 2025. *Bariatric (weight loss) surgery* updated 1 August 2025. URL: https://info.health.nz/health-topics/tests-and-treatments/surgery/bariatric-weight-loss-surgery (accessed 23 February 2026).
5. Health New Zealand. 2023. *Nutrition supplements after weight loss surgery* updated 7 January 2026. URL: https://info.health.nz/health-topics/tests-and-treatments/surgery/bariatric-weight-loss-surgery/nutrition-supplements-after-weight-loss-surgery (accessed 23 February 2026).
6. Therapeutic Goods Administration. 2019. *How are vitamins regulated in Australia?* updated 31 January 2025. URL: https://www.tga.gov.au/news/blog/how-are-vitamins-regulated-australia (accessed 23 February 2026).
7. Therapeutic Goods Administration. *Listed medicines* URL: https://www.tga.gov.au/products/medicines/listed-medicines (accessed 23 February 2026).
8. Therapeutic Goods Administration. 2020. *Understanding listed and registered complementary medicine regulation* updated 16 December 2025. URL: https://www.tga.gov.au/resources/guidance/understanding-listed-and-registered-complementary-medicine-regulation (accessed 23 February 2025).
9. Therapeutic Goods Administration. 2013. *Registered complementary medicines* 25 March 2013. URL: https://www.tga.gov.au/products/medicines/registered-complementary-medicines/overview/registered-complementary-medicines (accessed 23 February 2026).
10. Therapeutic Goods Administration. 2024. *Consultation: Proposed amendments to the Poisons Standard – ACMS #46 and Joint ACMS-ACCS #38 meetings, November 2024* 23 September 2024. URL: https://consultations.tga.gov.au/tga/scheduling-pre-meeting-november-2024/user_uploads/final---pre-meeting-public-notice---acms-46--accs-40--joint-38---november-2024---pdf.pdf (accessed 21 March 2025).
11. Therapeutic Goods Administration. 2025. *Notice of final decision to amend (or not amend) the current Poisons Standard in relation to pyridoxine, pyridoxal or pyridoxamine (vitamin B6)* 25 November 2025. URL: https://www.tga.gov.au/sites/default/files/2025-11/notice-final-decision-to-amend-current-poisons-standard-pyridoxine-pyridoxa-pyridoxamine-vitamin-b6.pdf (accessed 26 November 2025).
12. Therapeutic Goods Administration. 2026. *Medicines containing vitamin B6 (pyridoxine, pyridoxal or pyridoxamine)* 19 February 2026. URL: https://www.tga.gov.au/news/safety-updates/medicines-containing-vitamin-b6-pyridoxine-pyridoxal-or-pyridoxamine (accessed 19 February 2026).
13. Medsafe. 2024. *Suspected Medicines Adverse Reaction Search* 16 December 2024. URL: https://www.medsafe.govt.nz/SMARS/Default (accessed 16 February 2026).
14. ICH - Medical Dictionary for Regulatory Activities. *Standardised MedDRA Queries (SMQs).* URL: https://www.meddra.org/how-to-use/tools/smqs (accessed 16 February 2026).
15. ICH - Medical Dictionary for Regulatory Activities. 2025. *Introductory Guide for Standardised MedDRA Queries (SMQs) Version 28.1* September 2025. URL: https://admin.meddra.org/sites/default/files/guidance/file/SMQ_intguide_28_1_English.pdf (accessed 16 February 2026).
16. Therapeutic Goods Administration. 2025. *Notice of interim decision to amend (or not amend the current Poisons Standard in relation to pyridoxine, pyridoxal or pyridoxamine (vitamin B6)* 26 June 2025. URL: https://www.tga.gov.au/sites/default/files/2025-06/notice-interim-decision-amend-or-not-amend-current-poisons-standard-pyridoxine-pyridoxal-pyridoxamine-vitaminb6.pdf (accessed 10 October 2025).