

MEDICATION SAFETY COMMUNICATION

Information for health professionals in NSW public health organisations

Hydroxocobalamin 1 mg/1 mL solution for injection – 14 December 2023

Details of affected product(s)	Hydroxocobalamin acetate (Cobal-B12®) 1 mg/1 mL solution for injection – ARTG 285067 Hydroxocobalamin acetate (Vita-B12®) 1 mg/1 mL solution for injection – ARTG 172663 Hydroxocobalamin chloride (Hydexo-B12®) 1 mg/1 mL solution for injection – ARTG 161606 Hydroxocobalamin chloride (Neo-B12®) 1000 microg/1 mL injection ampoule – ARTG 121709
Reason for communication	Disruption to supply
Date issue made apparent	November 2023
Estimated resolution date	Q1, 2024

Main indications and use

Hydroxocobalamin is a form of vitamin B12 used for the:

- prevention and treatment of vitamin B12 deficiency
- prophylaxis and treatment of pernicious (Addisonian) anaemia and other macrocytic anaemias associated with vitamin B12 deficiency
- treatment of optic neuropathies (e.g., tobacco amblyopia and Leber's optic neuropathy)
- management of nitrous oxide neurotoxicity
- management of cyanide toxicity (at higher doses) – Note, a product available via the Therapeutic Goods Administration's Special Access Scheme is used for this indication.

Situation

There is a current disruption to the supply of all brands of hydroxocobalamin 1 mg/1 mL solution for injection due to manufacturing issues. The estimated return to supply date is variable throughout Q1, 2024 however there is potential for further delays. Supply of hydroxocobalamin (Cyanokit®) available via the Therapeutic Goods Administration's Special Access Scheme for the management of cyanide toxicity remains unaffected at the time of publication.

Alternative agents

At the time of publication, the following international alternatives have been approved for supply in Australia until **30 March 2024** under Section 19A (S19A) of the Therapeutic Goods Act and are available for purchase via Pro Pharmaceuticals Group:

- **Vitarubin®** (Hydroxocobalamin **acetate**) 1 mg/1 mL depot for injection from Switzerland.
- **Neo-Cytamen®** (hydroxocobalamin **chloride**) 1 mg/1 mL depot for injection from the United Kingdom.

Further S19A alternatives may become available – see [here](#) for further information.

Precautions, safety issues and other considerations associated with alternative products

The Australian registered products and S19A alternatives all contain hydroxocobalamin (either as acetate or chloride salt) and are identical in strength, formulation and storage requirements. However, there are differences in excipients and presentation. See **Table 1** on the next page for a comparison.

The S19A alternative Vitarubin, from Switzerland contains **methyl parahydroxybenzoate** as an additional excipient which may cause allergic reactions and bronchospasm. In addition to this, the Swiss alternative has **not** been tested for use in children and adolescents.

It is recommended that remaining supply of the Australian registered hydroxocobalamin products be reserved for paediatric populations and patients with a history of allergic reaction to methylparabens. In the case of complete disruption to supply of the Australian registered product, the Neo-Cytamen S19A alternative may be suitable for this patient cohort.

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Table 1. Comparison of Australian registered products and S19A alternatives.

	ARTG Product Cobal-B12	ARTG Product Hydroxo-B12	S19A alternative Neo-Cytamen (United Kingdom)	S19A alternative Vitarubin (Switzerland)
Active ingredient and strength	Hydroxocobalamin acetate 1 mg/1 mL	Hydroxocobalamin chloride 1 mg/1 mL	Hydroxocobalamin chloride 1 mg/1 mL	Hydroxocobalamin acetate 1 mg/1 mL
Form	Solution for intramuscular (IM) injection			
Excipients	<ul style="list-style-type: none"> sodium chloride 9 mg/mL glacial acetic acid water for injection 	<ul style="list-style-type: none"> sodium chloride 9 mg hydrochloric acid 	<ul style="list-style-type: none"> sodium chloride acetic acid water for injection 	<ul style="list-style-type: none"> sodium chloride tri-sodium acetate [also known as sodium acetate trihydrate] disodium edetate methyl parahydroxybenzoate (E 218, 1 mg/mL) glacial acetic acid water for injection
Storage	Store below 25°C. Protect from light.			
Presentation	Clear glass ampoule containing pale red liquid	Coloured glass ampoule containing dark red solution	Clear glass ampoule containing red solution	Amber glass ampoule containing solution for injection
Pack size	Pack of 3	Pack of 3	Pack of 5	Pack of 10
Additional documentation	ARTG listing	ARTG listing	Dear Health Care Professional letter	Dear Health Care Professional letter
Precautions and warnings	Not for intravenous use			<ul style="list-style-type: none"> Not for intravenous use Contains methyl parahydroxybenzoate Use not tested in children and adolescents
Labelling	English			Swiss (medicine name and strength can be deciphered)

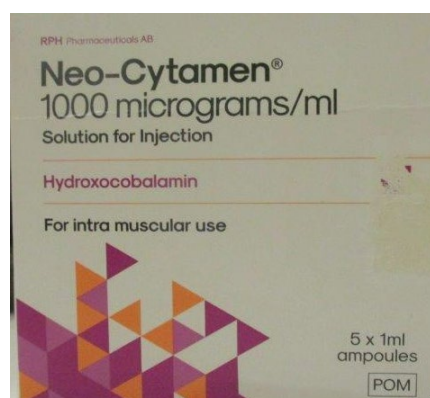


Figure 1. Artwork/packaging and ampoule images of available S19A alternatives Neo-Cytamen (left) and Vitarubin (right).

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Impacts of this communication on clinical practice

- Actions to address the disruption to the supply hydroxocobalamin should be planned and implemented at a local level by the Drug and Therapeutics Committee in consultation with the relevant clinicians.
- Alternatives are available and can be utilised by facilities after consideration of the above precautions and safety issues in addition to individual patient needs.

Associated regulatory or policy issues

[PD2022 032 Medication Handling](#)

[PD2019 019 Coordination of responses to urgent system-level medicine or medical device issues](#)

Key contacts

Clinical Excellence Commission (Medication Safety) – CEC-MedicationSafety@health.nsw.gov.au
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