



ProPharmaceuticalsGroup

Pro Pharmaceuticals Group Pty LTD
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Dear Healthcare Professional,

Shortage of COBAL-B12 INJECTION hydroxocobalamin acetate 1mg/ 1 mL solution for injection ampoule AUST R: 285067

Pro Pharmaceuticals Group recognises the importance of supplying essential medicines in Australia and would like to advise you the change in supply status of COBAL-B12 INJECTION hydroxocobalamin acetate 1mg/ 1 mL solution for injection ampoule AUST R: 285067 in Australia.

The Australian registered medicine, COBAL-B12 INJECTION hydroxocobalamin acetate 1mg/ 1 mL solution for injection ampoule AUST R: 285067, Solution Sponsor: Amdipharm Mercury Australia Pty Ltd is currently in shortage due to manufacturing issues.

Pro Pharmaceuticals Group has arranged for the supply of an alternative product, **VITARUBIN Depot hydroxocobalamin acetate 1mg/mL (Streuli Pharma, Switzerland)**. This product is NOT registered in Australia and supply is authorised under an exemption granted by the Therapeutic Goods Administration (TGA) under section 19A of the Therapeutic Goods Act 1989 until **30th March 2024** for the following indication(s):

Prophylaxis and treatment of pernicious (Addisonian) anaemia and other macrocytic anaemias associated with vitamin B12 deficiency. Treatment of optic neuropathies such as tobacco amblyopia and Leber's optic atrophy.

VITARUBIN Depot hydroxocobalamin acetate 1mg/mL (Streuli Pharma, Switzerland) is registered and marketed in Switzerland by Streuli Pharma AG.

The labelling is in Swiss language however the drug name and strength are identifiable in English. Approved specialist information document in English will be supplied with the product. A comparison table of differences between the products is given below.

As per the ARTG product information, IV administration of hydroxocobalamin injections is NOT recommended. Only administer VITARUBIN Depot hydroxocobalamin acetate 1mg/mL (Streuli Pharma, Switzerland) by INTRAMUSCULAR injection.

As per the official product information, the use and safety of VITARUBIN Depot hydroxocobalamin acetate 1mg/mL (Streuli Pharma, Switzerland) has not yet been tested in children and adolescents. Healthcare professionals should determine if this product is appropriate for their patient.

Please note: The section 19A approved product contains **methyl parahydroxybenzoate (E 218)**, which can cause allergic reactions, including delayed reactions, and in rare cases a spasm of the airways (bronchospasm). This excipient is declared on the product label in Swiss language. Healthcare professionals should determine if this product is appropriate for their patient.

Pro Pharmaceuticals Group recommends that healthcare professionals refer to the Australian approved Product Information for recommended dosing for various indications.

| | ARTG product COBAL-B12 INJECTION hydroxocobalamin acetate 1mg/ 1 mL solution for injection ampoule AUST R: 285067 | S19A Product VITARUBIN Depot hydroxocobalamin acetate 1mg/mL (Streuli Pharma, Switzerland) |
|------------------|--|--|
| Pack size | Pack of <u>3 ampoules</u> | Pack of <u>10 ampoules</u> |

| | | |
|-------------------|--|--|
| Excipients | sodium chloride glacial acetic acid for pH adjustment water for injections | sodium chloride tri-sodium acetate [<i>aka sodium acetate trihydrate</i>] disodium edetate methyl parahydroxybenzoate (E 218, 1mg/ml) glacial acetic acid water for injections |
|-------------------|--|--|

Reporting suspected adverse events is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with **VITARUBIN Depot hydroxocobalamin acetate 1mg/mL (Streuli Pharma, Switzerland)** must be reported by healthcare professionals, pharmacists, and patients to the TGA at <https://www.tga.gov.au/reporting-problems> or to Pro Pharmaceuticals Group on 1300077674 or email regulatory@propg.com.au

Any product complaints with **VITARUBIN Depot hydroxocobalamin acetate 1mg/mL (Streuli Pharma, Switzerland)** should be reported to Pro Pharmaceuticals Group on 1300 077674 or email regulatory@propg.com.au

For any orders please contact Pro Pharmaceuticals Group on 1300077674 or email orders@propg.com.au

Please forward this information to relevant staff members in your organisation. For further information, please contact Pro Pharmaceuticals Group on 1300077674 or email info@propg.com.au

Sincerely,
Sandip Manku – Director Pro Pharmaceuticals Group