MEDICATION SAFETY COMMUNICATION

Information for health professionals in NSW public health organisations

Folic acid (Phebra) 5 mg/mL injection – 2 May 2023	
Details of affected product(s)	Folic acid (Phebra) 5 mg/mL injection vial – ARTG 22852
Reason for communication	Discontinuation from the market due to commercial changes.
Date issue made apparent	April 2023
Estimated resolution date	Not applicable

Main indications and use

Folic acid injection is indicated for the treatment of folate deficiency megaloblastic anaemia due to malabsorption disorders, pregnancy and lactation, alcoholism, haemolytic anaemia, hyperthyroidism, exfoliative dermatitis and chronic infection.

Situation

The drug sponsor has advised that folic acid 5 mg/mL injection will be discontinued from the market due to commercial changes making it unviable to continue manufacturing. Discontinuation of this product will become effective on 31 May 2023 upon expiry of the remaining stock.

Alternative agents

- Phebra is the only sponsor that markets a folic acid 5 mg/mL injection product in Australia.
- Remaining stock of folic acid (Phebra) 5 mg/mL injection should continue to be used until exhausted or expired.
- An alternative product is available on the Australian Register of Therapeutic Goods (ARTG), folic acid (Biological Therapies) **15 mg/mL** injection vial – ARTG 106971.

Precautions, safety issues and other considerations associated with alternatives

Folic acid (Biological Therapies) 15 mg/mL injection:

- Clinicians should be alerted to the **difference in concentration** and the potential need to use a smaller volume to obtain the correct dose. See Australian Injectable Drugs Handbook for guidance on administration.
- Clinicians should also be alerted to the **difference in storage requirements** (refer to Table 1).
- This product may be confused for folinic acid (leucovorin calcium) 15 mg/2mL injection which is also stored in the refrigerator. Drug and Therapeutics Committees should determine whether there is a local need for re-labelling and other strategies to assist in product selection (e.g. shelf talkers) and education of staff prior to introduction of folic acid 15 mg/mL.
- Folic acid 15 mg/mL has been added to the NSW Medicines Formulary. The listing for folic acid 5 mg/mL will be retained until stock is exhausted.

Table 1. Comparison between folic acid injections

Supplier	**Phebra®** (ARTG 22852)	*ARTG listed alternative* **Biological Therapies®** (ARTG 106971)
Concentration	5 mg/mL	15 mg/mL
Preparation to achieve required concentration for intravenous infusion (100 microg/mL)	Dilute 5 mg vial to 50 mL with a compatible fluid	Dilute 15 mg vial to 150 mL with a compatible fluid
Presentation	1 mL of solution in amber glass vial	1 mL of solution in amber glass vial
Storage	Store below 25°C, protect from light	**Store at 2°C to 8°C**, protect from light

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Impacts of this communication on clinical practice

Actions to address the disruption to the supply of folic acid (Phebra) 5 mg/mL injection should be planned and implemented at a local level by the Drug and Therapeutics committees in consultation with relevant clinicians. An alternative product is available and can be utilised by facilities after consideration of the above precautions and safety issues. Local policies, guidelines and procedures pertaining to folic acid should be updated to reference the alternative product and ensure differences in concentration and storage requirements are addressed.

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
HealthShare NSW (Category Manager – Strategic Procurement) – Noman.Masood@health.nsw.gov.au

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