MEDICATION SAFETY COMMUNICATION

Information for health professionals in NSW public health organisations

DBL methotrexate vials (various strengths) – 16 July 2020	
Details of affected product(s)	DBL methotrexate 5 mg/2 mL vial – ARTG 16313 DBL methotrexate 50 mg/2 mL vial – ARTG 16314 DBL methotrexate 1 g/10 mL vial – ARTG 16312
Reason for communication	Disruption to supply due to manufacturing delay
Date issue made apparent	22 June 2020
Estimated resolution date	Late July 2020 (1 g/10 mL), August 2020 (5 mg/2 mL, 50 mg/2 mL)

Main therapeutic applications

Methotrexate is a folic acid antagonist used in the treatment of oncological and haematological malignancies. It is also utilised in ectopic pregnancy, rheumatological (e.g. psoriasis and rheumatoid arthritis) and gastrointestinal (e.g. Crohn's disease) indications. Methotrexate is administered via several routes including intravenous, intrathecal, subcutaneous and intramuscular injection.

Alternative agents

- DBL is the sole supplier of methotrexate 5 mg/2 mL vial for injection in Australia.
- An alternative of the 5 mg/2 mL strength (unregistered product through the Special Access Scheme) (from Belgium) may be available through Medsurge (labelled in Dutch).
- A full list of available registered alternatives can be found on the ARTG. Pre-filled syringe presentations may also be considered for certain indications.
- Baxter, Slade and/or other external compounders can also be contacted to determine availability of manufactured/prepacked alternatives.

Precautions and safety issues associated with alternative products

- Some facilities use methotrexate vials to prepare doses for intrathecal administration. If switching to an alternative product or strength for this purpose, Pharmacists should confirm that it is suitable for intrathecal administration by checking the Product Information. The tonicity of the injectable solution and absence of preservatives are important considerations.
- The SAS alternative of the 5 mg/2 mL strength through Medsurge is suitable for intrathecal administration as per the Product Information (PI). The excipients are the same as those present in the ARTG product, however **the PI for this product recommends that it should be diluted to a concentration of 1 mg/mL using physiological sodium chloride 0.9% prior to intrathecal administration.**
- The final volume of reconstituted products will be altered if a methotrexate product of a different concentration is used during the preparation process. Reconstituted products should be clearly labelled according to the National Standard for User-applied Labelling of Injectable Medicines, Fluids and Lines, Clinical Oncological Society of Australia's Guidelines for the Safe Prescribing, Dispensing and Administration of Cancer Chemotherapy and other relevant locally-endorsed guidelines.
- Where appropriate, commercially available pre-filled syringes can be used for approved indications and routes of administration. Patients should receive thorough education on; early signs and symptoms of toxicity, appropriate self-injection technique, management of spills and appropriate disposal.

Impacts of this communication on clinical practice

If supply of required methotrexate strength is exhausted, alternate strengths in vials or pre-filled syringe products (if appropriate) will need to be used during the period of supply disruption.

Associated regulatory or policy issues

PD2013_043 Medication Handling in NSW Public Health Facilities

PD2016_058 User-applied Labelling of Injectable Medicines, Fluids and Lines

Key contacts

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

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