



Safety Notice 006/16

Etopophos (etoposide phosphate) powder for injection vials and Vepesid (etoposide) capsules - Disruption to Supply

27 July 2016

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Director, Regulation and Compliance Unit
- Drug and Therapeutic Committees

Action required by:

- Chief Executives
- Directors of Clinical Governance

We recommend you also inform:

- Oncology units
- Directors of Medical Services
- Directors of Nursing and Midwifery
- Directors of Pharmacy
- Drugs and Therapeutics Committees and subcommittees

Expert Reference Group

Content reviewed by:

- Office of the Chief Health Officer
- Chief Pharmacist Unit
- Clinical Excellence Commission
- Cancer Institute

Clinical Excellence Commission

Tel. 02 9269 5500
Fax. 02 9269 5599

Email:
Cec-quality@health.nsw.gov.au

Internet Website:
<http://www.health.nsw.gov.au/quality/sabs>

Intranet Website
<http://internal.health.nsw.gov.au/quality/sabs/>

Review date

July 2017

Background

A shortage notification has been issued for Etopophos (etoposide phosphate) powder for injection and Vepesid (etoposide) Capsules due to an unexpected interruption in the supply of the active ingredient. The shortage is expected to continue until April 2017. Etopophos (etoposide phosphate) is used for the treatment of a number of conditions including small cell carcinoma of the lung, acute monocytic and myelomonocytic leukaemia, Hodgkin's disease, Non-Hodgkin's lymphoma and testicular tumours.

The affected products are:

ARTG No.	ARTG Label	Sponsor	Contains
57483	Etopophos etoposide 113.6 mg (equivalent to 100 mg etoposide) powder for injection vial	Bristol-Myers Squibb Australia	etoposide phosphate
77220	Etopophos etoposide 1 g (as phosphate) powder for injection vial	Bristol-Myers Squibb Australia	etoposide phosphate
10233	Vepesid etoposide 50 mg capsule blister pack	Bristol-Myers Squibb Australia	etoposide
10234	Vepesid etoposide 100 mg capsule blister pack	Bristol-Myers Squibb Australia	etoposide

As the shortage is due to an interruption in the supply of the active ingredient, etoposide phosphate preparations compounded by a licensed manufacturer under a contract will also be affected.

Etoposide phosphate is a pro-drug of etoposide and is not directly interchangeable with etoposide (113.6mg of etoposide phosphate is equivalent to 100mg of etoposide).

The following alternative etoposide injectable preparations are available:

ARTG No.	ARTG Label	Sponsor	Contains
11365	Etoposide injection 100 mg in 5 mL injection vial	Pfizer Australia Pty Ltd	etoposide
96641	Etoposide Ebewe etoposide 100 mg in 5 mL injection vial	Sandoz Pty Ltd	etoposide

The alternative etoposide injectable preparations may be less stable (increasing risk of precipitation) and require larger fluid volumes for administration (increasing risk of volume overload in some patients)^{1,2}. Etoposide must be administered by slow infusion, unlike etoposide phosphate which may be rapidly infused. There are no alternative oral capsules of etoposide available.

Detailed information regarding alternative etoposide injectable preparations and switching a patient from the oral to injectable form is available from the TGA: <https://www.tga.gov.au/alert/etopophos-etoposide-phosphate-powder-injection-vials-and-vepesid-etoposide-capsules>³

Further Information

- Therapeutic Goods Administration, Product Information, Etoposide Injection 100 mg/5 mL (Pfizer), http://tga-search.clients.funnelback.com/s/search.html?collection=tga-artg&profile=record&meta_i=11365
- Therapeutic Goods Administration, Product Information, Etoposide Ebewe etoposide 100 mg/ 5 mL (Sandoz), http://tga-search.clients.funnelback.com/s/search.html?collection=tga-artg&profile=record&meta_i=96641
- Therapeutic Goods Administration, 28 June 2016, Etopophos (etoposide phosphate) powder for injection vials and Vepesid etoposide capsules, <https://www.tga.gov.au/alert/etopophos-etoposide-phosphate-powder-injection-vials-and-vepesid-etoposide-capsules>

In preparation for the shortage Local Health Districts/Networks should:

- Distribute this safety notice and the link to the TGA website to all stakeholders and clinical departments affected by the anticipated shortage of Etopophos (etoposide phosphate).
- Develop a local plan to manage the supply shortage which should include:
 - an assessment of the current status of Etopophos (etoposide phosphate) availability in each facility
 - consideration of clinical implications of the shortage for patients treated in hospital and in the community
 - reviewing and adjusting protocols which include Etopophos (etoposide phosphate)
 - strategies to minimise the risk of precipitation, volume overload and incorrect infusion rates (especially the need for slow infusion) when the alternative etoposide preparations are used.
- Inform clinicians to ensure that the anticipated shortage is taken into consideration when planning treatment with Etopophos injection vials or Vepesid capsules.
- Inform patients affected by the shortage of potential changes to their treatment.
- Inform clinicians, stakeholders and clinical departments when supply of Etopophos injection vials and Vepesid capsules is reinstated.
- Ensure a system is in place to document actions taken.