



Etoposide preparations - Disruption to Supply - (Supersedes Safety Notice 006/16)

2 May 2017

Distributed to:

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

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

Clinical Excellence Commission

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Internet Website:
<http://www.health.nsw.gov.au/sabs/Pages/default.aspx>

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

Review date

September 2017

Background

Etoposide is a cytotoxic antineoplastic medicine 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.

Information regarding a shortage of Etopophos[®] (etoposide phosphate) powder for injection and Vepesid[®] (etoposide) Capsules was issued in July 2016 (SN 006/16). The shortage is now expected to continue until August/September 2017 (previously estimated to be resolved in April 2017). The shortage has also impacted on the availability of Etoposide[®] injection 100mg in 5 mL injection vial. See table on page 2 for availability.

There are no alternative oral capsules of etoposide available.

Precautions with etoposide injectable preparations

Etopophos[®] (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 alternative etoposide injectable preparations may be less stable on dilution (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.**

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

1. 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
2. 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
3. Therapeutic Goods Administration, 6 April 2017, 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>

Suggested actions by Local Health Districts/Networks:

1. Distribute this safety notice and the link to the TGA website to all stakeholders and clinical departments affected by the shortage of Etopophos[®] (etoposide phosphate).
2. Revise local plans to manage the supply shortage in view of the extended disruption to supply.
3. Inform clinicians to ensure that the extended disruption to supply is taken into consideration when planning treatment with etoposide preparations.
4. Inform patients affected by the shortage of potential changes to their treatment
5. Inform clinicians, stakeholders and clinical departments when supply of etoposide phosphate and oral etoposide is reinstated.
6. Ensure a system is in place to document actions taken.



Safety Notice 007/17

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The affected products are:

ARTG No.	ARTG Label	Sponsor	Contains	Availability
57483	Etopophos etoposide 113.6 mg (equivalent to 100 mg etoposide) powder for injection vial	Bristol-Myers Squibb Australia	etoposide phosphate	Not available until August 2017
77220	Etopophos etoposide 1 g (as phosphate) powder for injection vial	Bristol-Myers Squibb Australia	etoposide phosphate	Not available until August 2017
10233	Vepesid etoposide 50 mg capsule blister pack	Bristol-Myers Squibb Australia	etoposide	Limited stock available. Return to normal expected September 2017.
10234	Vepesid etoposide 100 mg capsule blister pack	Bristol-Myers Squibb Australia	etoposide	Limited stock available. Return to normal expected September 2017.
11365	Etoposide injection 100 mg in 5 mL injection vial	Pfizer Australia Pty Ltd	etoposide	Not available until May 2017
96641	Etoposide Ebewe etoposide 100 mg in 5 mL injection vial	Sandoz Pty Ltd	etoposide	Currently available

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.