4 April 2024

Shortage of BUSULFAN ACCORD busulfan 60 mg/10 mL concentrated injection vial (AUST R 300848) and alternative supply arrangement under Section 19A of the Therapeutic Goods Act

Dear Healthcare Professional,

This communication is sent by ORSPEC Pharma to notify your organisation that due to the shortage of **BUSULFAN ACCORD busulfan 60 mg/10 mL concentrated injection vial (AUST R 300848)** ORSPEC Pharma has arranged the supply of an alternative product on a temporary basis.

Busulfan for injection 60mg/10mL vial (SteriMax, Canada) is NOT registered in Australia and supply is granted under an approval granted by the Therapeutic Goods Administration (TGA) under Section 19A (s19A) of the Therapeutic Goods Act, 1989 until **30 August 2024.**

Busulfan for injection 60mg/10mL vial (SteriMax, Canada) is approved under s19A for *use in combination with cyclophosphamide, melphalan or fludarabine in conditioning prior to haematopoietic stem cell transplantation.*

The s19A approved Canadian product is identical in active ingredient, strength and dose form to the Australian registered product.

Please note the following information regarding differences between BUSULFAN ACCORD busulfan 60 mg/10 mL concentrated injection vial (AUST R 300848) and Busulfan for injection 60mg/10mL vial (SteriMax, Canada):

	BUSULFAN ACCORD busulfan 60 mg/10 mL concentrated injection vial (AUST R 300848)	**Busulfan for injection 60mg/10mL vial (SteriMax, Canada)**
Dosage	The Busulfan Accord daily dose may be given as a single three-hour infusion once daily (od) over 4 consecutive days for a total of 4 doses. Alternatively, the daily dose may be divided and given as a two to three hour infusion every 12 hours (bd) for four days, giving a total of 8 doses, or every 6 hours (qid) for four days, giving a total of 16 doses.	Busulfan for Injection should be administered intravenously via a central venous catheter as a two-hour infusion every 6 hours x 4 consecutive days for a total of 16 doses.
Preparation and Administration	Small volumes may be administered over 2 or 3 hours using electric syringes. In this case infusion sets with minimal priming space should be used (i.e 0.3-0.6 mL), primed with drug solution prior to beginning the actual Busulfan Accord infusion and then flushed with sodium chloride (0.9%) solution for injection or glucose (5%) solution for injection.	No information on small volume dosing.

	A nylon or polyester filter should be used if Busulfan Accord is administered via an in-line filter or a filter fitted with an infusion set.	
Storage	Unopened vials of Busulfan Accord Injection must be stored at 2-8°C in a refrigerator. (Do not freeze.) To reduce microbiological hazard, use as soon as practicable after preparation. If storage is necessary, hold at 2-8°C for not more than 15 hours. The chemical and physical stability of the diluted solution has been demonstrated for 8 hours at 20-25°C.	Unopened vials of Busulfan for Injection must be stored under refrigerated conditions between 2-8ºC (36-46 ºF). Do not freeze. Busulfan for Injection diluted in 0.9% Sodium Chloride Injection is stable at refrigerated conditions (2-8˚C) for up to 12 hours but the infusion must be completed within that time. Busulfan for Injection diluted in 0.9% Sodium Chloride Injection or 5% Dextrose Injection is stable at room temperature (25ºC) for up to 8 hours but the infusion must be completed within that time.

Busulfan for injection 60mg/10mL vial (SteriMax, Canada) is registered in Canada and is packaged in English and French labelling. For dosing and administration information, please refer to the Australian Product Information for **BUSULFAN ACCORD busulfan 60 mg/10 mL concentrated injection vial (AUST R 300848)** available at https://www.ebs.tga.gov.au/

Adverse Event Reporting

Reporting any suspected adverse event is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with **Busulfan for injection 60mg/10mL vial (SteriMax, Canada),** should be reported by healthcare professionals and patients to ORSPEC Pharma on 024 339 4239 or email at customerservice@orspecpharma.com. Alternatively, this information can be reported to the TGA at https://www.tga.gov.au/reporting-problems

Please forward this information to relevant staff members in your organisation.

For further information, please contact ORSPEC Pharma on 024 339 4239 or email customerservice@orspecpharma.com.

Yours sincerely,

Deon Scheepers
Managing Director
ORSPEC Pharma