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)** |
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| **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. |

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| | 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.)<br>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.<br>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.<br>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.<br>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