PLEASE DISTRIBUTE TO OTHER HEALTHCARE PROFESSIONALS IN YOUR FACILITY

Pfizer Australia Pty Ltd
ABN: 50 008 422 348
38 - 42 Wharf Road
West Ryde NSW 2114
Australia

7 April 2017

Dear Healthcare Professional,

Shortage of DANTRIUM® powder for injection 20 mg (for intravenous injection) vials AUST R 14435 and alternative supply arrangement under Section 19A of the Therapeutic Goods Act

The Australian registered medicine, **DANTRIUM® powder for injection 20 mg (for intravenous injection) AUST R 14435** sponsored by Pfizer Australia Pty Ltd is unavailable due to an unexpected third party manufacturing issue. Supply of DANTRIUM® powder for injection 20 mg is expected to resume late December 2017.

Presentation	Pack Size	Pfizer Item Code	Out of Stock Date	Back in Stock Date
DANTRIUM® (dantrolene sodium) powder for injection 20 mg vials	1 x 6 vials	0117519	Now	Late Dec 17

Pfizer Australia has been able to arrange supply of an alternative product, **RYANODEX® (dantrolene sodium) for injectable suspension (250mg)** on a temporary basis. This product is NOT registered in Australia and supply is authorised under an exemption granted by the Therapeutic Goods Administration (TGA) under section 19A of the *Therapeutic Goods Act 1989* until late May 2017.

RYANODEX® (dantrolene sodium) for injectable suspension (250mg) is registered and marketed in the United States.

Presentation	Pack Size	Pfizer Item Code	Available from	Cease supply
RYANODEX® (dantrolene sodium) for injectable suspension (250mg)	1 x 1 vials	F000034704	Mid April 17	Late May 17

Please note the following information regarding differences between RYANODEX® (dantrolene sodium) for injectable suspension (250mg) and DANTRIUM® powder for injection 20 mg (for intravenous injection) AUST R 14435.

Product characteristic	RYANODEX®	DANTRIUM®
Presentation	Sterile **250mg** lyophilised powder, 20 mL vial injectable suspension for IV use	Sterile 20mg lyophilised powder, 65ml vial for IV use
Formulation	Active: **250mg** dantrolene sodium; Inactive: 125mg mannitol, 25mg polysorbate 80, 4mg povidone K12, NaOH, HCl.	Active: 20mg dantrolene sodium; Inactive: 3g mannitol, NaOH
Approved indication/ route of administration	Malignant Hyperthermia (MH), prevention of MH in patients at high risk	Malignant Hyperthermia crisis
Dosing	Dose at 1mg/ kg with max cumulative dose 10mg/kg	Dose at 1mg/ kg with max cumulative dose 10mg/kg
Reconstitution/ Administration	Mix with **5mL** WFI; produces orange coloured suspension. For Intravenous push. Final concentration = 50mg/mL, pH 10.3.	Mix with 60 mL WFI. Shake until solution is clear. Continuous rapid Intravenous push. Final concentration ~ 0.33mg/mL, pH 9.5.
Warning/ Precautions/ Contraindications	Similar. Check full Product Information before prescribing.	Similar. Check full Product Information before prescribing
Storage/ Handling	Use within 6 hrs @ 20C – 25C, Protect from light	Protect from light, use within 6 hrs @ 15C – 25C

WARNING: **Healthcare professionals should take note of specific instructions for the preparation and administration of RYANODEX® (dantrolene sodium) for injectable suspension (250mg). Please refer to the package insert before use:**

- RYANODEX® (dantrolene sodium) can be used instead of DANTRIUM® for treatment of an MH crisis
- The reconstituted suspension is a slightly more alkaline solution than DANTRIUM® and has a much higher concentration of the active ingredient. Care should be taken to prevent extravasation.
- Care should be taken to change the instructions for reconstitution from DANTRIUM® where the initial dose would be up to 9 vials, to RYANODEX® (dantrolene sodium) where the dose would be less than one vial.
- If MH crisis cards are used in the institution, they should be altered appropriately.
- Recommended guidelines, including MH crisis cards, for the treatment of Malignant Hyperthermia are available from the Australian and New Zealand Malignant Hyperthermia Group **www.malignanthyperthermia.org.au**

Complete information regarding the approved indications for DANTRIUM® powder for injection 20 mg can be located in the Product Information available at www.pfizer.com.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 RYANODEX® (dantrolene sodium) for injectable suspension (250mg) should be reported by healthcare professionals and patients to Pfizer on 1800 675 229 or by email address AUS.AEReporting@pfizer.com or to the TGA at: https://www.tga.gov.au/reporting-problems.

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

For further information, please contact Pfizer Medical Information on 1800 675 229 or by email: medicalaffairs.anz@pfizer.com.

Yours sincerely,

Wayne Lee
Associate Medical Director
Pfizer Essential Health
Pfizer Australia