21 November 2022

LINK
A CLINIGEN COMPANY

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RE: Shortage of DANTRIUM dantrolene sodium hemiheptahydrate 20mg powder for injection vial and alternative supply arrangement under Section 19A of the *Therapeutic Goods Act*.

Dear Healthcare Professional,

This notification is sent by LINK to inform your organisation that due to the shortage of Australian registered **DANTRIUM dantrolene sodium hemiheptahydrate 20mg powder for injection vial (AUST R 14435)**, LINK has arranged the supply of an alternative product, ***REVONTO dantrolene sodium for injection 20mg/vial*** registered and marketed in *the United States of America.*

REVONTO dantrolene sodium for injection 20mg/vial 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 **31 March 2023.**

REVONTO dantrolene sodium for injection 20mg/vial is indicated, along with appropriate supportive measures, for:

> *The management of the fulminant hypermetabolism of skeletal muscle characteristic of malignant hyperthermia crisis. It should be administered by intravenous injection as soon as the malignant hyperthermia reaction is recognised (i.e. tachycardia, tachypnea, central venous desaturation, hypercarbia, metabolic acidosis, skeletal muscle rigidity, increased utilisation of anaesthesia circuit carbon dioxide absorber, cyanosis and mottling of the skin, and, in many cases, fever).*

The s19A approved *US* product is identical in active ingredient, strength, excipient ingredients, reconstitution and administration details to the Australian registered product.

Please refer to the Australian Product Information for **DANTRIUM dantrolene sodium hemiheptahydrate 20mg powder for injection vial (AUST R 14435)** (available at https://www.ebs.tga.gov.au) when prescribing and administering ***REVONTO dantrolene sodium for injection 20mg/vial.***

REVONTO dantrolene sodium for injection 20mg/vial are registered in ***the United States of America*** with the outer package and package insert both in *English*. The active ingredient, strength and dosage form included on the vial label are in English.

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 ***REVONTO dantrolene sodium for injection 20mg/vial*** should be reported by healthcare professionals and patients to Link Healthcare Medical Information. This information can also be reported to the TGA at https://www.tga.gov.au/reporting-problems.

Link Healthcare Medical Information can be contacted by phone on 1800 181 060 or via email at medinfo@linkhealthcare.com.au.

Link Healthcare Customer Service contact details

Link Healthcare Customer Service can be contacted via phone on 1800 181 060 or via email at customerservice@linkhealthcare.com.au.

Please contact Link Healthcare Customer Service for further information.

We would appreciate if you could distribute this information to those in your organisation who would be affected by the shortage of the Australian registered **DANTRIUM dantrolene sodium hemiheptahydrate 20mg powder for injection vial (AUST R 14435).**

Yours sincerely,

C Griffin

Charlotte Griffin
Medicine Access Associate