22 December 2022

Discontinuation of RYTHMODAN disopyramide 100 mg capsule 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 discontinuation of **RYTHMODAN disopyramide 100 mg capsule (AUST R 13537).** ORSEPC Pharma has arranged the supply of an alternative product on a temporary basis.

RYTHMODAN disopyramide 100 mg capsule (UK), are NOT registered in Australia and supply is granted under an exemption granted by the Therapeutic Goods Administration (TGA) under Section 19A of the *Therapeutic Goods Act 1989* until **30 June 2023.**

RYTHMODAN disopyramide 100 mg capsule (UK), are approved for use under Section 19A for the following indications:

> *Rythmodan capsules are indicated for the management of documented ventricular arrhythmias, such as sustained ventricular tachycardia, which are judged to be life threatening. Because of its proarrhythmic potential, the use of disopyramide is not recommended for lesser arrhythmias.*
>
> *Treatment of asymptomatic ventricular premature contractions should be avoided.*
>
> *In patients with structural heart disease, proarrhythmia and cardiac decompensation are a special risk associated with antiarrhythmic medicines. Special caution should be exercised when prescribing disopyramide for these patients*

RYTHMODAN disopyramide 100 mg capsule (UK), are registered in the United Kingdom and are packaged in English language. Please note the following similarities and differences between, **RYTHMODAN disopyramide 100 mg capsule (AUST R 13537)** and **RYTHMODAN disopyramide 100 mg capsule (UK)** to be supplied under section 19A:

4/6 Carnarvon Road
West Gosford, NSW, 2250
www.orspecpharma.com

	RYTHMODAN disopyramide 100 mg capsule (AUST R 13537)	**RYTHMODAN disopyramide 100 mg capsule (UK)**
Pack Size	100 capsules per blister pack	PVC Blister containing 84 capsules
Storage	Store below 30°C	Store below 25°C

For dosing and administration information, please refer to the Australian Product Information for **RYTHMODAN disopyramide 100 mg capsule (AUST R 13537)** 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 **RYTHMODAN disopyramide 100 mg capsule (UK),** should be reported by healthcare professionals and patients to ORSPEC Pharma on 024 339 4239 or email at sas@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 sas@orspecpharma.com.

Yours sincerely,

Deon Scheepers
Managing Director
ORSPEC Pharma