Department of Health & Social Care

NHS England

Medicine Supply Notification

MSN/2024/075

Disopyramide (Rythmodan Retard®) 250mg modified-release tablets and disopyramide (Rythmodan®) 100mg capsules.

Tier 2 – medium impact*
Date of issue: 24/06/2024
Link: Medicines Supply Tool

Summary

- Disopyramide (Rythmodan Retard®) 250mg modified-release tablets are out of stock until mid-July 2024.
- Disopyramide (Rythmodan®) 100mg capsules will be out of stock from mid-July 2024 until mid-January 2025.
- From mid-July, disopyramide (Rythmodan Retard®) 250mg modified-release tablets can support a partial increase in demand.
- Alternative treatments to disopyramide remain available (see Supporting information).
- Unlicensed imports of disopyramide 100mg capsules and disopyramide 250mg MR tablets have been sourced, lead times vary (see Supporting information).
- Unlicensed specials of disopyramide 25mg/5ml & 50mg/5ml oral suspension are available, lead times vary (see Supporting information).

Actions Required

Clinicians should evaluate whether disopyramide is the most appropriate treatment before initiating new patients. During this period, clinicians should not initiate patients on 100mg capsules unless alternative treatment options are not appropriate (see further information below under advice 'for patients prescribed Rythmodan® 100mg capsules).

Until mid-July, for patients prescribed Rythmodan Retard® 250mg modified-release tablets, clinicians should:

- Establish if they have sufficient supply to last until the resupply date.
- Consider prescribing unlicensed products only where licensed alternatives are not appropriate. Prescribers should work with local pharmacy teams to ensure orders are placed within appropriate time frames as lead times may vary (see Supporting information).
- If unlicensed imports are unavailable, consider unlicensed specials of disopyramide liquid (25mg/5ml & 50mg/5ml), ensuring suitability by reviewing excipients content based on the patient's age and weight.

Until Jan 2025, for patients prescribed Rythmodan®100mg capsules clinicians should:

*Classification of Tiers can be found at the following link:
https://www.england.nhs.uk/publication/a-guide-to-managing-medicines-supply-and-shortages/

- If appropriate, consider prescribing mavacamten where disopyramide has been prescribed for hypertrophic obstructive cardiomyopathy. Note: mavacamten is not routinely used in patients less than 18 years of age (see Supporting information).
- Convert patients where suitable to Rythmodan Retard® 250mg modified release tablets at same total daily dose if the formulation allows, or as close as possible, and titrate the dose as needed (see Supporting information).
- Counsel patients on any change in formulation and/or dose change and advise them to report adverse effects and/or recurrence of symptoms after switching.
- Consider prescribing unlicensed products only where licensed alternatives are not appropriate or unavailable. Prescribers should work with local pharmacy teams to ensure orders are placed within appropriate time frames as lead times may vary (see Supporting information).
  If unlicensed imports or if the 250mg tablets are unavailable/unsuitable, consider unlicensed specials of disopyramide liquid (25mg/5ml & 50mg/5ml), ensuring suitability by reviewing excipients content based on the patient's age and weight.

Seek advice from cardiology specialists on management of paediatric patients, unstable patients or patients newly started on treatment, or where there is uncertainly or concern about switching formulation and or/dose conversion.

Supporting information

Clinical Information

Disopyramide is licensed for the treatment of cardiac arrhythmias, with dose adjusted according to response. In addition to the immediate release capsule formulation, it is also formulated as a modified-release tablet. As disopyramide tends to be a last line antiarrhythmic agent, alternative treatment options are limited, need to be assessed on an individual basis, and require specialist input.

Disopyramide is used in specialist clinics for symptomatic control of hypertrophic obstructive cardiomyopathy (off-label use). Mavacamten is prescribed by specialists for the treatment of hypertrophic obstructive cardiomyopathy and may be considered a potential alternative subject to suitable specialist referral and pharmacogenetic testing.

Disopyramide conversion between immediate release and modified release preparations

Half-life: 5 to 8 hours

Immediate release 100mg capsules
Licensed dose range: 300 mg to 800 mg daily in divided doses (usually every 6 to 8 hours)

Modified release 250mg tablets
One side has a break-line, and the tablets are licensed to be halved.
Licensed dose range: 250-375 mg (one to one and a half tablets) twice daily.

Immediate release capsules total daily dose (mg)	Modified release tablet dose regimen (mg)	Modified release tablet total daily dose after switch (mg)
300	125 BD or 250 am 125 pm	250 or 375
400	250 am 125 pm or 250 BD	375 or 500
500	250 BD	500
600	625	625
700	750	750
800	750	750

Disopyramide conversion between immediate release and specials liquid preparations

Immediate release capsules total daily dose (mg)	25mg /5mL Oral Suspension daily dose	50mg /5mL Oral Suspension daily dose
300	75mg QDS*	75mg QDS*
400	100mg QDS*	100mg QDS*
500	125mg QDS*	125mg QDS*
600	150mg QDS*	150mg QDS*
700	175mg QDS*	175mg QDS*
800	200mg QDS*	200mg QDS*

*** Clinicians can change to total daily dose as a TDS dosing regimen if easier.**

Links to further information

SmPC disopyramide preparations
SmPC mavacamten preparations
BNF disopyramide

Guidance on ordering and prescribing unlicensed imports

The following specialist importers have confirmed they can source unlicensed disopyramide 100mg capsules and 250mg MR tablets. Please note there may be other companies that can also source supplies:

- Alium Medical (100mg capsules)
- Chemys (100mg capsules)
- Genetech (both capsules & tablets)
- Mawdsleys Unlicensed (both capsules & tablets)
- Target Healthcare (both capsules & tablets)

The following specials manufacturers have confirmed they can source unlicensed disopyramide liquid (25mg/5ml and or 50mg/5ml oral suspension). Please note there may be other companies that can also source supplies:

- Nova Laboratories
- PCCA
- Temag Target Healthcare

Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Trust or local governance procedures. Unlicensed imports do not undergo any central quality assessment or suitability evaluation. Therefore, any import must be locally assessed in line with local unlicensed medicines processes. Please see the links below for further information:

- The supply of unlicensed medicinal products, Medicines and Healthcare products Regulatory Agency (MHRA)
- Professional Guidance for the Procurement and Supply of Specials, Royal Pharmaceutical Society
- Prescribing unlicensed medicines, General Medical Council (GMC),

Enquiries

If you have any queries, please contact DHSCmedicinesupplyteam@dhsc.gov.uk.