

**From the Chief Medical Officer  
Dr Michael McBride**



Department of  
**Health**

An Roinn Sláinte

Mánnystrie O Poustie

[www.health-ni.gov.uk](http://www.health-ni.gov.uk)

**HSS(MD) 12/2019**

**For Action:**

Chief Executives of HSC Trusts  
GP Medical Advisers, Health and Social Care Board  
All General Practitioners and GP Locums (for onward  
distribution to practice staff)  
Director of Integrated Care, Health and Social Care  
Board  
Chief Executive RQIA (for onward transmission to all  
independent providers including independent  
hospitals)  
Assistant Director of Pharmacy and Medicines  
Management, Health and Social Care Board (for  
onward distribution to Community Pharmacies)

Castle Buildings  
Stormont Estate  
BELFAST  
BT4 3SQ

Tel: 028 90 520559  
Fax: 028 90 520573  
Email: [Michael.McBride@health-ni.gov.uk](mailto:Michael.McBride@health-ni.gov.uk)

Our Ref: HSS(MD) 12/2019  
Date: 18 June 2019

**PLEASE SEE ATTACHED FULL CIRCULATION LIST**

Dear Colleague

**DISOPYRAMIDE 100MG AND 150MG CAPSULES SUPPLY DISRUPTION –  
ACTIONS FOR HEALTHCARE PROFESSIONALS WHO PRESCRIBE, DISPENSE  
OR ADMINISTER DISOPYRAMIDE 100MG OR 150MG CAPSULES**

This letter is to inform you of a current supply issue affecting disopyramide capsules due to a manufacturing delay of UK licensed stock. Disopyramide is licensed for the treatment of cardiac arrhythmias and is often employed as a last line antiarrhythmic agent. Dosage is adjusted according to the response of the patient.

Sanofi and Mylan are the only licensed UK suppliers of disopyramide 100mg capsules; Mylan are the sole UK supplier of disopyramide 150mg capsules. It is anticipated that current stock of 100mg will be depleted by mid-June and 150mg by mid-August. Further supplies are currently anticipated to be available to the market late July (100mg) and mid-September (150mg).

Supplies are available from specialist importers on an 'unlicensed' basis during the shortage period. Prescribers should liaise with their pharmacist to clarify local availability of products before prescribing, and should take into account local governance procedures for the use of unlicensed medicines and the relevant GMC guidance (available at <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for->

[doctors/prescribing-and-managing-medicines-and-devices/prescribing-unlicensed-medicines\)](#)

### **Actions for health care professionals**

- Prescribers and pharmacists should identify all patients currently prescribed disopyramide 100mg or 150mg capsules. Early contact should be made with the patient or patient's carer to determine if they have enough disopyramide capsules to last for the duration of the shortage.
- If the patient has sufficient supplies to last through the affected period, then no further action is required.
- If a patient does not have sufficient supplies, the following advice should be followed:
  - i. Switch patients to an unlicensed import.
  - ii. If unlicensed imports are not considered suitable then patients should be referred to secondary care specialists for further management.
  - iii. Patients should be prescribed a licensed product if available, therefore if patients are switched to an unlicensed preparation they should be switched back to a licensed product when supplies are back in stock, which is likely to be late July for the 100mg capsules and mid-September for the 150mg capsules.

If prescribers have any concerns about switching a patients' medication, they should consult the patient's secondary care specialist prescriber to seek support.

Please refer to the attached DHSC Supply Disruption Alert for further information. This alert can also be accessed at

<https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=102869>

Yours sincerely



**DR MICHAEL McBRIDE**  
Chief Medical Officer



**MRS CATHY HARRISON**  
Acting Chief Pharmaceutical Officer

### **Circulation List**

Executive Medical Director/Director of Public Health, Public Health Agency (for onward distribution to all relevant staff)

Director of Nursing, Public Health Agency

Directors of Pharmacy HSC Trusts

Director of Social Care and Children, HSCB

Family Practitioner Service Leads, Health and Social Care Board (for cascade to GP Out of Hours services)  
Medical Directors, HSC Trusts (for onward distribution to all Consultants, gynaecology, hepatology, A&E staff, hospital pharmacy, and sexual health/family planning centres)  
Nursing Directors, HSC Trusts (for onward distribution to all Community Nurses, and Midwives)  
RQIA (for onward transmission to all independent providers including independent hospitals)  
Medicines Management Pharmacists, HSC Board (for cascade to prescribing advisers)  
Regional Medicines Information Service, Belfast HSC Trust  
Regional Pharmaceutical Procurement Service, Northern HSC Trust  
Professor Donna Fitzsimons, Head of School of Nursing and Midwifery QUB  
Professor Sonja McIlfattrick, Head of School of Nursing, University of Ulster  
Caroline Lee, CEC  
Donna Gallagher, Open University  
Professor Paul McCarron, Head of School of Pharmacy and Pharmaceutical Sciences, UU  
Professor Carmel Hughes, Head of School, School of Pharmacy, QUB  
Professor Colin Adair, Director of the NI Centre for Pharmacy Learning and Development, QUB

This letter is available on the Department of Health website at  
<https://www.health-ni.gov.uk/topics/professional-medical-and-environmental-health-advice/hssmd-letters-and-urgent-communications>

# Supply Disruption Alert

SDA/2019/002

Issued: 14 June 2019 at 13:00

Valid until: 30/09/2019

## Disopyramide 100mg/150mg capsules – Supply Disruption

### Summary

- Disopyramide 100mg capsules will be out of stock from approximately mid-June until late-July.
- Disopyramide 150mg capsules will be out of stock from approximately mid-August until mid-September.
- Supplies are available from specialist importers on an 'unlicensed' basis.

### Action

1. Prescribers and pharmacists should identify all patients currently prescribed disopyramide 100mg/150mg capsules. Early contact should be made with the patient or patient's carer to determine if they have enough disopyramide capsules to last for the duration of the shortage.
2. If the patient has sufficient supplies to last through the affected period, then no further action is required.
3. If a patient does not have sufficient supplies, the following advice should be followed:
  - i. Switch patients to an unlicensed import.
  - ii. If unlicensed imports are not considered suitable then patients should be referred to secondary care specialists for further management.
  - iii. Patients should be prescribed a licensed product if available, therefore if patients are switched to an unlicensed preparation they should be switched back to a licensed product when supplies are back in stock, which is likely to be late July for the 100mg capsules and mid-September for the 150mg capsules.

If prescribers have any concerns about switching a patients' medication, they should consult the patient's secondary care specialist prescriber to seek support.

#### Action, to be taken by

- NHS Regional Offices
- Community pharmacists
- General practitioners
- General practice nurses
- Consultant cardiologists
- Consultant electrophysiologists
- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners
- Pharmaceutical advisors
- Pharmacists
- Hospital pharmacies
- Hospital pharmacists
- Community nurses
- District nurses

Please also send on to others you feel may need to take actions.

**Deadlines for actions**

Actions underway: 18/06/2019  
Actions completed: 30/09/2019

**Product details**

Sanofi Rythmodan (disopyramide) 100mg capsules  
Mylan disopyramide 100mg capsules  
Mylan disopyramide 150mg capsules

**Problem / background**

There is a short-term supply issue affecting disopyramide capsules due to a manufacturing delay of UK licensed stock. Sanofi and Mylan are the only licensed UK suppliers of disopyramide 100mg capsules; Mylan are the sole UK supplier of disopyramide 150mg capsules. It is anticipated that current stock of 100mg will be depleted by mid-June and 150mg by mid-August. Further supplies are currently anticipated to be available to the market late July (100mg) and mid-September (150mg).

Disopyramide is licensed for the treatment of cardiac arrhythmias and is often employed as a last line anti-arrhythmic agent. Dosage is adjusted according to the response of the patient.

**Alternative Products**

Unlicensed product:

Unlicensed specialist importers are able to source disopyramide from abroad. Pharmacists will know how to source these unlicensed and specials products and should be able to advise you further. Before prescribing, you should liaise with your pharmacist to clarify local availability of products.

When prescribing and dispensing unlicensed preparations, prescribers and pharmacists should always ensure the following:

- Clear patient consent has been sought for use of an unlicensed preparation.
- If a switch is made to a different product, prescribers, carers and patients must be made aware of the change and it should be confirmed that patients are taking the correct dose.
- Patients are supplied sufficient quantity of a specific unlicensed preparation to cover until licensed disopyramide returns to stock.
- Any decision to prescribe an unlicensed medicine must take into account the relevant GMC guidance and NHS Trust / Local governance procedures. Please see link to GMC guidance:  
<https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/prescribing-and-managing-medicines-and-devices/prescribing-unlicensed-medicines>

**Distribution**

- MHRA
- NHS England Patient Safety
- NHS England EPRR
- Chief Medical Officer
- NHS England – National Clinical Director
- Directors of Procurement – Devolved Authorities

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

**Trusts (NHS boards in Scotland)**

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- A&E consultants
- A&E departments
- A&E nurses
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Chief pharmacists
- Clinical governance leads
- Clinical Procurement Specialists [NEW]
- Community hospitals
- Community nurses
- Coronary care departments
- Coronary care nurses
- Hospital at home units
- Hospital pharmacies
- Hospital pharmacists
- Medical directors
- NHS walk-in centres
- Paramedics
- Pharmaceutical advisors
- Pharmacists
- Purchasing managers
- Risk managers
- Supplies managers
- Walk-in centres

**NHS England area teams**

CAS liaison officers for onward distribution to all relevant staff including:

- Community pharmacists
- General practitioners
- General practice managers
- General practice nurses

**Independent distribution****Establishments registered with the Care Quality Commission (CQC) (England only)**

- Adult placement
- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Clinics
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive Supply Disruption Alerts directly from the Medicine and Healthcare Regulatory Agency's Central Alerting System (CAS) by sending an email to: [safetyalerts@mhra.gov.uk](mailto:safetyalerts@mhra.gov.uk) and requesting this facility.

## Enquiries

**England**

Send enquiries about this notice to the DHSC Supply Resilience Team, quoting reference number SDA/2019/002 or email: [supplyresiliencemd@dhsc.gov.uk](mailto:supplyresiliencemd@dhsc.gov.uk).

Addressees may take copies for distribution within their own organisations