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 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.

Addressees may take copies for distribution within their own organisations