

From the Chief Medical Officer
Dr Michael McBride

HSS(MD)26/2019



Department of
Health

An Roinn Sláinte

Mánnystrie O Poustie

www.health-ni.gov.uk

For Action:

Chief Executives of HSC Trusts
Chief Executive RQIA (*for onward transmission to all independent providers including independent hospitals*)

PLEASE SEE ATTACHED FULL CIRCULATION LIST

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Your Ref:

Our Ref: HSS(MD)26/2019

Date: 25 October 2019

Dear Colleague

**MITOMYCIN-C KYOWA - SUPPLY DISRUPTION ALERT
ACTIONS FOR ALL HEALTHCARE PROFESSIONALS IN SECONDARY OR
SPECIALIST HEALTHCARE SETTINGS WHO PRESCRIBE, COMPOUND,
DISPENSE OR ADMINISTER MITOMYCIN**

This letter is to inform you of a current supply issue affecting Mitomycin-C 2mg, 10mg and 20mg powder for solution for injection and Mitomycin-C 40mg powder for intravesical solution marketed by Kyowa Kirin. All strengths are unavailable with no date for resupply until further notice. This supply issue is due to quality control release and manufacturing concerns.

No alternative supplies of UK licensed mitomycin are available in sufficient quantities to support this gap in supply. Imports of unlicensed mitomycin powder for solution for injection and intravesical solution are available but may not be sufficient to meet normal demand.

Actions for healthcare professionals

All health care professionals in secondary or specialist healthcare services who prescribe, compound, dispense or administer mitomycin should:

- Ensure orders are placed for unlicensed imports immediately, in line with normal demand for Mitomycin-C. Lead times vary so organisations may wish to consider sharing stock locally until imports are received. Information about availability of unlicensed imports is available from the Regional

Pharmaceutical Procurement Service, who can be contacted by email at RPHPS.Admin@northerntrust.hscni.net.

- Contact individual importer companies for most up to date information on import availability and lead times.
- Not order mitomycin 40 mg, powder and solvent for intravesical solution from Medac unless you are an existing customer. Medac have insufficient stocks to cover any increase in demand.
- Ensure aseptic units are made aware of this supply interruption and requirements for process changes are reviewed and implemented. The Commercial Medicines Unit at NHS England is communicating directly with commercial compounders about this supply issue.
- Where demand exceeds available supplies, in discussion with local clinical specialists, consider prioritising the stock available (both remaining supplies and unlicensed imports) for clinical indications deemed appropriate locally.
- Consider appropriate alternatives in discussion with local specialists where unlicensed supplies are deemed unsuitable or where there are insufficient supplies available to meet normal demand.

Please refer to the attached DHSC Supply Disruption Alert for further information.

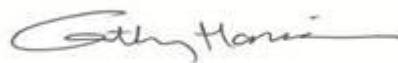
This alert can also be accessed at

<https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=102910>

Yours sincerely



Dr Michael McBride
Chief Medical Officer



Mrs Cathy Harrison
Acting Chief Pharmaceutical Officer

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>

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 McIlpatrick, 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



Supply Disruption Alert

SDA/2019/006

Issued: 24 October 2019

Valid until: 31 January 2020

Mitomycin-C Kyowa all strengths – Supply Disruption Alert

Summary

- Mitomycin-C 2mg, 10mg, 20mg powder for solution for injection and Mitomycin-C 40mg powder for intravesical solution marketed in the UK by Kyowa Kirin is unavailable with no date for resupply until further notice.
- This supply issue is due to quality control release and manufacturing concerns.
- No alternative supplies of UK licensed mitomycin are available in sufficient quantities to support this gap in supply
- Imports of unlicensed mitomycin powder for solution for injection and intravesical solution are available but may not be sufficient to meet normal demand.

Action

All healthcare professionals in secondary or specialist healthcare services who prescribe, compound, dispense or administer mitomycin should:

- Ensure orders are placed for unlicensed imports immediately, in line with normal demand for Mitomycin-C. Lead times vary so organisations may wish to consider sharing stock locally until imports are received.
- Contact individual importer companies for most up to date information on import availability and lead times.
- Not order mitomycin 40 mg, powder and solvent for intravesical solution from Medac unless you are an existing customer. Medac have insufficient stocks to cover any increase in demand.
- Ensure aseptic units are made aware of this supply interruption and requirements for process changes are reviewed and implemented. The Commercial Medicines Unit at NHS England is communicating directly with commercial compounders about this supply issue.
- Where demand exceeds available supplies, in discussion with local clinical specialists, consider prioritising the stock available (both remaining supplies and unlicensed imports) for clinical indications deemed appropriate locally.
- Consider appropriate alternatives in discussion with local specialists where unlicensed supplies are deemed unsuitable or where there are insufficient supplies available to meet normal demand.

Deadlines for actions

Actions initiated: 24 October 2019
Actions completed: 31 January 2020

Product details

Mitomycin-C Kyowa 2mg powder for solution for injection 10 vials
Mitomycin-C Kyowa 10mg powder for solution for injection 1 vial
Mitomycin-C Kyowa 20mg powder for solution for injection 1 vial
Mitomycin-C Kyowa 40mg powder for intravesical solution 1 vial

Problem / background

Kyowa Kirin are the sole supplier of Mitomycin-C 2mg, 10mg and 20mg powder for solution for injection and hold a significant market share of Mitomycin-C 40mg powder for intravesical solution. This gap in supply is due to quality control release and manufacturing concerns. NHS England & Improvement, the Department of Health and Social Care and the Medicines and Healthcare products Regulatory Agency (MHRA) continue to work closely with Kyowa Kirin on resolving this issue as quickly as possible.

Distribution

Trusts (NHS boards in Scotland)

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

- Chief pharmacists
- Clinical governance leads
- Clinical Procurement Specialists
- Colposcopy departments
- Haematologists
- Hospital pharmacies
- Hospital pharmacists
- Medical oncologists
- Medical oncology, directors of
- Oncology nurse specialists
- Ophthalmic nurses
- Ophthalmologists
- Ophthalmology departments
- Ophthalmology, directors of
- Pharmaceutical advisors
- Pharmacists
- Purchasing managers
- Radiation & medical oncology departments
- Radiation oncologists
- Radiation oncology, directors of
- Sterile services departments
- Supplies managers
- Urological surgeons
- Urological surgery, directors of
- Urology departments

Enquiries

England

Enquiries from NHS Trusts in England should in the first instance be directed to you trust pharmacy team who will escalate issues to the Regional Procurement Lead and national teams if required.

REGION	Full Name	Email
East Midlands	Andi Swain	andi.swain@nhs.net
East of England	James Kent	james.kent@southend.nhs.uk
London	Jackie Eastwood	jacqueline.eastwood@lpp.nhs.uk
North East	David Cook	David.Cook@nth.nhs.uk
North West	Glenn Harley	Glenn.Harley@liverpoolft.nhs.uk
South Central	Alison Ashman	Alison.Ashman@berkshire.nhs.uk
South East Coast	Richard Bateman	richard.bateman2@nhs.net
South West	Danny Palmer	Danny.Palmer@UHBristol.nhs.uk
West Midlands	Davinder Manku	davinder.manku@nhs.net
Yorkshire&Humber	David Allwood	davidallwood@nhs.net

All other organisations should send enquiries about this notice to the DHSC Supply Resilience Team, quoting reference number **SDA/2019/006**

Email: supplyresiliencemd@dhsc.gov.uk