Department of Health & Social Care

NHS

UPDATE- Supply Disruption Alert

SDA/2019/006 (U) Issued: 07 November 2019 Valid until: 31 January 2020

Mitomycin-C Kyowa all strengths – Supply Disruption Alert - Update

Summary

- All unexpired batches of Kyowa Kirin Mitomycin-C, as listed below, are subject to a MHRA Class 2 recall EL (19)A/33.
- Kyowa Kirin will be unable to support the UK market for at least 12 months.
- UKMi, in full consultation with clinical experts in the fields of Oncology and Ophthalmology, has drafted clinical advice to support local management of this supply disruption, should sufficient imports not be available to support full demand https://www.sps.nhs.uk/articles/shortage-of-mito…wa-all-strengths/
- This is an update to SDA/2019/006, please refer to the original SDA for more information on this supply disruption.

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;
- work with Regional Pharmacy Procurement Specialists to share available stock between Trusts to minimise impact on patients partway through a mitomycin containing regimen; and
- in discussion with local clinical specialists, consider ringfencing the stock available for priority indications and agreeing alternatives for others, as outlined in the clinical memo.

Deadlines for actions

Actions initiated:	11 November 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

The above products have been recalled by Kyowa Kirin Ltd as a precautionary measure due to deviations from the aseptic manufacturing processes during the manufacture of the sterile active pharmaceutical ingredient and excipients.
NHS England & Improvement and the Department of Health and Social Care are working with alternative marketing authorisation holders Medac and Accord to make mitomycin products available to the UK market in the next two to six months, respectively, to mitigate the impact of this supply disruption.

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
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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(U)**

Email: supplyresiliencemd@dhsc.gov.uk