



Dear Colleague

MEDICINE SUPPLY ALERT NOTICE

Medicine in short supply: Mitomycin-C Kyowa® 2mg powder for solution for injection; Mitomycin-C Kyowa® 10mg powder for solution for injection; Mitomycin-C Kyowa® 20mg powder for solution for injection; and Mitomycin-C Kyowa® 40mg powder for intravesical solution

Priority: Level 3
Valid until: October 2020

Issue

1. All formulations of Mitomycin-C Kyowa® (2mg, 10mg and 20mg) powder for solution for injection and Mitomycin-C 40mg powder for intravesical solution marketed in the UK by Kyowa Kirin are anticipated to be out of stock, with no date for resupply until further notice. This supply issue is due to quality control release and manufacturing concerns.

2. No alternative supplies of UK licensed Mitomycin-C Kyowa® are available in sufficient quantities to support the resulting 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.

Affected stock

3. The following preparations are affected:

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

25 October 2019

Addressees:

For action

NHS Directors of Pharmacy
NHS Medical Directors
Pharmacy Primary Care Leads
Medicines Information
Pharmacists
Community Pharmacy Scotland
NHS National Procurement
Scottish Prescribing Advisor
Network

For information

Director Practitioner Services,
NHS NSS
NHS Scotland Chief Executives
NHS Director of Finance

General Enquiries to:

Pharmacy & Medicines Division
St Andrew's House
EDINBURGH, EH1 3DG

Tel: 0131 244 2075

Email:

PharmacyTeam@gov.scot

www.gov.scot

Actions

4. All healthcare professionals in secondary or specialist healthcare services who prescribe, compound, dispense or administer Mitomycin-C 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-C 40mg 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.
- 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.

Further background

5. Kyowa Kirin are the sole supplier of Mitomycin-C Kyowa® 2mg, 10mg and 20mg powder for solution for injection and hold a significant market share of Mitomycin-C Kyowa® 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.

6. Mitomycin-C Kyowa® 2mg, 10mg and 20 mg powder for solution for injection are used for certain types of cancer in combination with other drugs or after primary therapy has failed. It has been successfully used to improve subjective and objective symptoms in a wide range of neoplastic conditions. Mitomycin-C Kyowa® 40 mg, powder for intravesical solution is used as a single agent in the treatment of superficial bladder cancer.

Impact

7. All Kyowa Kirin product currently in the supply chain is affected, including batches due for manufacture and those already manufactured.

Enquiries

8. Enquiries should in the first instance be directed to National Procurement. NSS.NHSSMedicineShortages@nhs.net

NHS Circular:
MSAN (2019) 7

Action

9. Health Board Medical Directors and Directors of Pharmacy are asked to cascade this Medicines Supply Alert Notice to the relevant healthcare professionals in their Health Board area.

10. Healthcare professionals are asked to note the content and actions outlined in this circular and Annex.

Yours sincerely,

A handwritten signature in cursive script, appearing to read 'Rose Marie Parr'.

Rose Marie Parr
Chief Pharmaceutical Officer/
Deputy Director Pharmacy & Medicines Division

Medicines Shortages Response Group (Scotland) priority definitions

LEVEL	DESCRIPTION	POTENTIAL RESPONSES
Level one (low impact)	Supply problem with a short duration (up to one month) where <u>immediately available measures are expected to be sufficient</u> and there is minimal additional management requirement.	Business as usual. Response likely to involve using the same medicine. <ul style="list-style-type: none"> Alternative strength/formulation available to meet demand, potentially from other suppliers.
Level two (medium impact)	Supply problem where <u>alternatives in the same therapeutic class are available but which may require some management</u> such as switching to those alternatives, which may include unlicensed medicines. Level two shortages also include level one shortages that continue for more than a month.	Business as usual. Response not likely to require a change in the class of medicine. <ul style="list-style-type: none"> Alternative strength/formulation available but clinical advice is required to help manage the switch. Alternative medicine in the same therapeutic class. Unlicensed alternatives may be available.
Level three (high impact)	Supply problems where there are <u>limited or no alternatives in the same therapeutic class and which require significant management</u> , potentially including changes in clinical practice or operational direction or that have patient safety implications. Level three shortages also include level two shortages for medicines used in <u>life saving conditions</u> such as anaphylaxis or involving <u>patient groups considered as vulnerable</u> , such as neonates, pediatrics or people with learning disabilities.	Serious shortage situation. Response likely to require a change in the therapeutic class of medicine. <ul style="list-style-type: none"> Alternative therapeutic class of medicine available. The use of a 'serious shortage protocol'. Additional clinical advice. Exceptional MHRA regulatory measures. Issuing a Medicine Supply Alert Notice (MSAN) to the NHS via the MSAN system.
Level four (critical impact)	Supply problems where there is <u>no viable therapeutic alternative</u> and were responses may also require support from the wider NHS and outside the health system and / or which trigger the use of national resilience structures.	Very serious shortage situation. Wider burden on NHS and public sector. <ul style="list-style-type: none"> Non-medicine support provided to patients. National Resilience procedures potentially activated – including links with agencies outside NHS. Additional project management or communications support may be required.