29 August 2019

Direct Healthcare Professional Communication

Mitomycin-C Kyowa 40 mg restricted to intravesical administration only for treatment of superficial bladder cancer

Dear Healthcare Professional,

Kyowa Kirin Limited, in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA) would like to inform you of the following:

Summary

- Following observation of increasing sub-visible particles in the drug product on storage, the indication and route of administration for Mitomycin-C Kyowa 40 mg powder for solution for injection have been restricted.
- The therapeutic indication of the Mitomycin-C Kyowa 40 mg product is restricted to the treatment of superficial bladder cancer only (see Summary of Product Characteristics).
- The product name has changed to “Mitomycin-C Kyowa 40 mg, powder for intravesical solution” to reflect the restriction in route of administration to intravesical route only.
- Mitomycin-C Kyowa 40 mg should not be administered by any other route.
- There is no change to the current dosing schedule for intravesical administration.
- **The therapeutic indications and administration routes for Mitomycin-C Kyowa 2 mg, 10 mg and 20 mg products remain unchanged.**

Background

An increase in Sub-visible particles has been observed for Mitomycin-C Kyowa 40 mg products during routine stability testing. The sub-visible particles are observed at levels above specification limits, in the drug product after reconstitution. The levels of particles observed could potentially have an adverse impact on patient safety when the drug product is administered intravenously

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or intra-arterially. As a precautionary measure, this has led to restrictions in the indication and route of administration and a change in the name of the product. Patients receiving the Mitomycin-C Kyowa 40 mg product via the intravesical route for superficial bladder cancer are not considered to be at risk of harm from exposure to these sub-visible particles.

Changes to the Summary of Product Characteristics

The product "Mitomycin-C Kyowa, 40 mg, powder for solution for injection" has been removed from the Summary of Product Characteristics (SmPC) for "Mitomycin-C Kyowa". The product name has changed to "Mitomycin-C Kyowa 40 mg, powder for intravesical solution" to reflect the restriction in route of administration to intravesical route only. The indication is restricted to the treatment of superficial bladder cancer only. i.e. Mitomycin-C Kyowa 40 mg, powder for intravesical solution is indicated: *"As a single agent in the treatment of superficial bladder cancer. In addition it has been shown that post-operative instillations of Mitomycin-C Kyowa 40 mg can reduce recurrence rates in newly diagnosed patients with superficial bladder cancer."*

A separate SmPC has been created for "Mitomycin-C Kyowa 40 mg, powder for intravesical solution". Please see enclosed SmPC.

The Summary of Product Characteristics for the 2 mg, 10 mg and 20 mg products is available here: https://www.medicines.org.uk/emc/product/4262/smpc

Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to any medicines to the MHRA through the Yellow Card Scheme. You can also report defective medicines to the Yellow Card Scheme.
Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalization, and those that are considered medically significant for any other reason

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- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

It is easiest and quickest to report ADRs online via the Yellow Cards website https://yellowcard.mhra.gov.uk/ or via the Yellow Card app available from the Apple App Store or Google Pay Store.

Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary)
- by emailing yellowcard@mhra.gov.uk
- at the back of the British National Formulary (BNF)
- by telephoning the Commission of Human Medicines (CHM) free phone line: 0800-731-6789 or
- by downloading and printing a form from the Yellow Card website (see link above)

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name.

Adverse events should also be reported to Kyowa Kirin by emailing medinfo@kyowakirin.com or on tel. +44 (0)1896 664000.

Company contact points

If you have any questions or require further information, please contact:

Kyowa Kirin Medical Information: Email: medinfo@kyowakirin.com; or, Tel: +44 (0)1896 664000

Yours faithfully,

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