9 October 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 Health Products Regulatory Authority (HPRA), 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 10 mg 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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Job Number: KK/IRE/MIT/0002
Date of preparation: October 2019

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 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 10 mg product is available here: www.hpra.ie

Call for reporting

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;
Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

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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