CENTRAL PROCUREMENT & SUPPLIES UNIT
MINISTRY FOR HEALTH
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Important information on mitomycin-containing medicinal products of medac GmbH – restrictions for intravenous use

Dear Healthcare Professionals,

medac GmbH would like to inform you of the following:

Summary
Herewith we would like to inform you that for all Mitomycin-containing medicinal products of medac GmbH, intended for intravenous application, a particle filter must be used (5 µm pore size) until further notice.

This relates to the following indications:

As monochemotherapy or in combined cytostatic chemotherapy in adults with:

- advanced colorectal carcinoma
- advanced gastric carcinoma
- advanced and/or metastatic breast carcinoma
- advanced oesophageal carcinoma
- advanced cervical carcinoma
- non-small-cell bronchial carcinoma
- advanced pancreatic carcinoma
- advanced tumours of the head and neck.

However, for intravesical administration for relapse prevention in adults with superficial urinary bladder carcinoma after transurethral resection based on current evidence there is no risk for patients' safety.

The ability to supply the Mitomycin products from medac GmbH is still guaranteed.

Background information
During an ongoing stability program, some batches showed an out-of-specification result with regards to visible particles. These were identified as Mitomycin polymers. In the case of intravesical administration, no negative effects on patients are expected. Nevertheless, particles could lead to thromboembolic events in capillary arteries in case of intravenous administration.
The above-mentioned restrictions for use are based on this possible risk for patients' safety in case of intravenous use only. The risk of thromboembolic events can be effectively prevented by using an appropriate particle filter (5 µm pore size).

Call for reporting
Please report any suspected adverse reactions associated with the use of Mitomycin-containing medac products in accordance with the national spontaneous reporting system

National contact point

Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form available online at http://www.medicinesauthority.gov.mt/adrportal and sent to Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN or sent by email to: postlicensing.medicinesauthority@gov.mt

Yours sincerely,

Bernardette Rossi

Regulatory Affairs & Pharmacovigilance
Central Procurement and Supplies Unit | Ministry for Health

The CPSU declares that the supplier for product/s included in the above application will always keep him informed of any Pharmacovigilance issues related to the product for which a marketing authorization is being requested.

The CPSU also declares that it has in place a system for handling of pharmacovigilance issues, and that the marketing authorization holder of the original product marketed in Malta has been notified about the product being put on sale in Malta, in accordance with the Parallel Importation of Medicinal Products Regulations.