DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION (DHPC)
IN AGREEMENT WITH THE ITALIAN MEDICINES AGENCY (AIFA)

27 Gennaio 2022

MITUROX (MITOMYCIN 40 MG), POWDER AND SOLVENT FOR INTRAVESICAL SOLUTION: UROLOGICAL CATHETER INCLUDED NOT SPECIFIC FOR INTRAVESICAL INSTILLATION

Dear Healthcare professional,

Medac Pharma s.r.l., in agreement with the Italian Medicines Agency (AIFA) the would like to inform you of the following:

Summary

- **possible unsuitability of the catheter in the authorised packaging of the medicinal product Miturox (mitomycin 40 mg), powder and solvent for intravesical solution**

This Direct Healthcare Professional Communication is intended to draw attention to the possible unsuitability for intravesical instillation of the Nelaton catheter CH 10 catheter contained in the authorized packaging of the medicinal product Miturox (mitomycin 40 mg), powder and solvent for intravesical solution, together with the solvent bag.

Specifically, it has recently been shown that the urological catheter included in the package (Nelaton catheter CH 10) has been tested by the manufacturer for urinary drainage but not specifically for intravesical instillation.

To date we have not received any reports of adverse events or complaints that could indicate an incompatibility of the catheter with the instillation of Miturox.

To avoid a possible shortage of mitomycin-based medicinal products and thus to ensure therapeutic continuity for patients being treated, it is considered appropriate not to interrupt the distribution of Miturox packs.

Users are therefore invited to assess the need to use an alternative catheter for intravesical instillation of the medicinal product in question.

Call for reporting

The reporting of suspected adverse reactions after the authorisation of a proprietary medicinal product is important. It allows continuous monitoring of the risk/benefit ratio of the medicine itself. Healthcare

professionals are reminded to continue to report any suspected adverse reactions via the Italian Medicines Agency reporting system: https://www.aifa.gov.it/content/segnalazioni-reazioni-avverse

AIFA takes the opportunity to remind all Healthcare Professionals of the importance of reporting suspected adverse drug reactions, as an indispensable tool to confirm a favorable benefit/risk ratio in the real conditions of use.

Reports of Suspected Adverse Reaction from drugs should be sent to the Pharmacovigilance Manager of the Structure to which the Operator belongs.

This Direct Healthcare Professional Communication is also published on the AIFA website (http://www.aifa.gov.it) and it's consultation is recommended for the best professional information and citizen service.