Direct Healthcare Professional Communication

Recommendations to avoid potentially fatal dosing errors when using methotrexate for inflammatory diseases

Dear Healthcare Professional,

Medac GmbH in agreement with the Scientific Centre of Drug and Medical technology Expertise after Academician E. Gabrielyan CJSC would like to inform you of the following:

Summary

- Dosing errors with serious consequences, including fatalities, have been reported when methotrexate intended for once-weekly use in inflammatory diseases was taken daily.
- Only physicians with expertise in using methotrexate-containing medicines should prescribe them.
- Healthcare professionals who prescribe or dispense methotrexate for inflammatory diseases should
    - provide to the patient/carer complete and clear dosing instructions on the once-weekly dosing;
    - check carefully at every new prescription /dispensing that the patient/carer understands that the medicine must be used once weekly;
    - decide together with the patient/carer on which day of the week the patient uses methotrexate;
    - inform the patient/carer of signs of overdose and instruct them to promptly seek medical advice in case of suspected overdose.

Background on the safety concern

Methotrexate is authorised for two different groups of indications, each of them with a different dosing schedule:

- For the treatment of cancer in which frequency depends on the regimen and can require daily administration of methotrexate.
- For the treatment of inflammatory diseases including rheumatoid arthritis, psoriasis, which require once-weekly use.

Despite measures already taken to prevent dosing errors, serious, sometimes fatal, cases continue to be reported, in which patients being treated for inflammatory diseases have taken methotrexate daily instead of once weekly. A safety review performed at EU level found that these errors can occur at all stages of the medication process.

Therefore, further measures to prevent dosing errors will be introduced, including prominent warnings on outer and inner packaging and updates to the summary of product characteristics and package leaflet. For oral formulations, there will be educational materials for healthcare professionals and a patient card will be provided with each package. In addition, tablets will only be available in blister packs.

Call for reporting

Reporting of suspected adverse reactions after registration of drug is important. It allows to control the ratio benefit/risk of drug. Please, report to Health Care Professionals about adverse reactions.

You may contact to Scientific Centre of Drug and Medical technology Expertise CJSC via following contacts,

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