

Educational Material to Healthcare Professionals (HCPs)

To minimize the risk the following educational material has been prepared to increase the awareness of healthcare professionals (HCPs) and patients on the risk of medication errors with methotrexate for intramuscular, intravenous, intraarterial or intrathecal routes following inadvertent administration of the physician recommended dose. Severe, life-threatening and fatal cases of overdose have been reported for methotrexate injection dosage forms in those cases. These overdose cases could occur in patients taking methotrexate for treatment of certain types of cancer such as breast cancer or for treatment of severe psoriasis.

Methotrexate is indicated for:

- Treatment of certain types of cancer such as breast cancer
- In smaller doses it can be used to treat severe psoriasis

It is important to note that the patient doctor will work out the correct dose of methotrexate injection for you and how often it must be given since the dose of medicine given. The educational material for HCPs should be read in conjunction with the Summary of Product Characteristics (SmPC) for methotrexate. The information regarding this risk of overdose is included in the Special warnings and precautions for use and Overdose sections of the SmPC.

Methotrexate is a cytotoxic agent, daily administration of a weekly dose can lead to overdose and to serious adverse outcomes, including death. Elderly patients are especially susceptible to serious toxicities. Despite risk minimisation measures are already in place, errors continue to be reported.

The occurrence of this medication error may occur at any point in therapy. Physicians and nurses should:

- Specify the indication, strength and dose for patients and pharmacists within the prescription.
- Verify dosing and administration instructions for methotrexate injection by at least two HCPs individuals.
- Provide clear directions on prescriptions for methotrexate:
 - Include the strength and dose in mg.
 - Do not use abbreviations.
- Physicians should carefully review prescribing and dosing instructions of methotrexate with patients/relatives/carers and indicate the specific day of the week to take medication with every new/repeat prescription.
 - Highlight the importance of taking methotrexate as prescribed (emphasize the danger with taking daily or extra doses).
 - Ensure patients are aware about the "Patient alert card". Transfer of care is a vulnerable stage in the medication process and patient alert card is especially helpful at this stage.
- Remind patients to review the patient alert card that will be included in/with the packaging when they receive their medication from the pharmacy and contact their physician promptly if the signs and symptoms of overdose occur.

- Ensure availability of appropriate rescue procedure (Ref: SmPC). Folinic acid is indicated to diminish the toxicity and counteract the effect of inadvertently administered overdoses of methotrexate.

Call for reporting

Suspected adverse reactions and **any medication error** should be reported to:

- The National Pharmacovigilance & Drug safety Centre (NPC) at Saudi Food and Drug Authority (SFDA)
SFDA Call Center: 19999
Toll Free Phone: 8002490000
Fax: +966-11-2057662
E-mail: npc.drug@sfd.a.gov.sa
Website: <http://ade.sfd.a.gov.sa/>
- Pharmacovigilance Department in the company
E-mail: SAU.AEReporting@pfizer.com

**This patient card is approved by the Saudi Food and Drug Authority (SFDA)
For extra copies, please contact Pfizer Saudi Limited at +966 12 2293500**