Direct Healthcare Professional Communication

19-9-2019

Recommendations to avoid potentially fatal dosing errors when using methotrexate "METHOTREXATE "EBEWE " for autoimmune diseases

Dear Healthcare Professional,
Sandoz Company in agreement with the Saudi Food & Drug Authority 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 autoimmune diseases was taken daily.
- Only physicians with expertise in using methotrexate-containing medicines should prescribe them.
- Healthcare professionals who prescribe or dispense methotrexate for autoimmune diseases should
    - provide to the patient/carer complete and clear dosing instructions on the once weekly dosing;
    - check carefully at every new prescription /dispensation 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 in the EU for two different groups of indications, each of them with a different administration schedule:
Severe generalised, otherwise therapy-resistant psoriasis, including psoriatic arthritis; autoimmune diseases such as rheumatoid arthritis (RA).

Malignant tumours and haemoblastoses treated with combination chemotherapy, in which an oral Methotrexate treatment is necessary. Despite measures already taken to prevent dosing errors, serious, sometimes fatal, cases continue to be reported, in which patients being treated for autoimmune 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 SPC 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
Suspected adverse reactions and **any medication error** should be reported in accordance with the national spontaneous reporting system:

Novartis Consulting AG, Patient Safety Department:
Phone: +996112658100
Toll free number: 8001240078
Mobile: 0545544426 or 0508035430
Fax: +966112658107
Email: adverse.events@novartis.com
Website: www.report.novartis.com

National Pharmacovigilance Center (SFDA):
Toll free phone: 8002490000
Fax: +966112057662
E-mail: npc.drug@sfda.gov.sa
Website: https://ade.sfda.gov.sa

Yours faithfully,

Malak Alowais
Patient Safety Manager (QPPV)
Novartis Saudi Arabia

Alowais Malak
Digitally signed by Alowais Malak
DN: dc=com, dc=novartis, ou=people, ou=GD, serialNumber=1834851, cn=Alowais Malak
Date: 2019.09.30 23:39:14 +03'00'