Checklist for Physicians who prescribe Methotrexate - Information to minimise the risk of potentially fatal dosing errors

METHOTREXATE TABLETS ADMINISTRATION ONCE A WEEK

Measures for preventing potentially fatal dosing errors resulting from more frequent administration

Please read this information carefully before prescribing methotrexate. This guide is not a substitute for Methotrexate Summary of Product Characteristics (SmPC). For full prescribing information and dosage recommendations of Methotrexate, please refer to the SmPC.

This checklist is provided for physicians who prescribe and work with patients who use methotrexate. The main objective of this guide is to help mitigate against medication errors, specifically overdose, which can result in toxicity and significant patient morbidity and mortality.

Oral methotrexate for treatment of non-oncological indications is administered on a once-weekly basis. The unusual weekly dosing schedule of methotrexate can be confusing for patients and healthcare professionals and has resulted in medication errors, some of which have been fatal. Errors occur at all stages in the medication use process, including errors at prescribing, dispensing and administration by patients, caregivers or healthcare professionals. Errors can occur both at the start of treatment or at any time when therapy is well established. Any change is critical, e.g. from prefilled syringes (administration subcutaneously) to tablets, or a change in institution or caregiver.

Communication plays a crucial role. Healthcare professionals can improve safety by providing patients/caregivers clear verbal and written instructions about how and when to take their methotrexate dose.

Treating physician

Only physicians with expertise in using methotrexate and full understanding of the risks of methotrexate therapy should prescribe these products.

The prescriber should ensure that patients or their carers will be able to comply with the once weekly regimen.

Inform patient and their carers to be alert for any symptoms suggestive of methotrexate toxicity and instruct them to promptly seek medical advice in case of suspected toxicity. Symptoms of toxicity are e.g. sore throat, fever, mouth ulcers, diarrhoea, vomiting, skin rashes, bleeding or unusual weakness.

During treatment, patients must be appropriately monitored so that signs of possible toxic effects or adverse reactions can be detected and evaluated with minimal delay. Patient should be reminded of importance of regular check-ups, including laboratory tests.

Checklist for Prescriber

Actions to be taken	Completed
Counselling Actions	
Provide the patient/carer complete and clear verbal and written confirmation on the 'once weekly' dosing regimen; include the indication.	
Educate patients and their families/caregivers about the importance of adhering to the correct dose and frequency of administration	
Educate patients and their families/caregivers on the signs and symptoms of intoxication and what action to take in the event of an overdose	
Check at every appointment that the patient/carer understands that the medicine must be taken once weekly and not more frequently.	
Presciption Actions	
Ensure required blood tests have been carried out.	
Explicitly write the dose (the strength and number of tablets) and the frequency of administration e.g. 'WEEKLY' on prescription	
Decide together with the patient/caregiver when the weekly dose should be taken and write on the prescription a day of the week (in full, no abbreviations), e.g. "Tuesday"	
Document dose changes on a new prescription to advise pharmacists of intention to adjust dose	
Double check prescription "**right strength ✓ right dose ✓ right frequency = weekly✓**"	
Do not prescribe the dose as a divided or split dose. This has been identified as a risk factor for medication error.	

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Patient Alert card

A patient alert card will be added to the outer package of methotrexate tablets.This card can be easily removed so that patient can always carry it with them at all times.

Until the new packs of Methotrexate tablets are made available, the patient alert cards will be distributed in pharmacies.

The Patient Alert card is a tool to:

- Remind patients/caregivers to take the product only once weekly
- Remind patients of the day of the week methotrexate treatment should be taken.
- inform patients on the symptoms of toxicity and steps to be taken should symptoms arise
- Remind patients to show the card and alert any healthcare professionals not familiar with their methotrexate treatment about their once weekly dosing schedule (e.g. on hospital admission, change of caregiver)

Reporting suspected adverse reactions and incidents of incorrect frequency of administration of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Healthcare professionals are asked to report any suspected adverse reactions via:

HPRA Pharmacovigilance,

Website: www.hpra.ie

Suspected adverse drug reactions may also be reported to the Medical Information Service teams of any of the below mentioned marketing authorisation holders:

Marketing Authorisation Holder	Medicinal Product Full Name	Marketing Authorisation Number	Email contact	Telephone number
Amdipharm Limited, Ireland	Methotrexate 2.5 mg Tablets	PA1142/030/001	medicalinformation@advanzpharma.com	+352 1800 851 119
Orion Corporation	Methotrexate 2.5mg Tablets Methotrexate 10mg Tablets Methotrexate Orion 2.5mg Tablets Methotrexate Orion 10mg Tablets	PA 1327/009/001 PA 1327/009/002 PA 1327/019/001 PA 1327/019/002	ie.medicalinformation@orionpharma.com	+44 1635 520 300
Accord Healthcare Ireland Ltd.	Methotrexate 2.5 mg Tablets Methotrexate 10 mg Tablets	PA 2315/062/001 PA 2315/062/002	medinfo@accord-healthcare.com or by completing the online form at www.accord-healthcare.ie/drug-reaction-report	+44 1271 385 257

The educational materials/patient alert card will be available in electronic format on www.hpra.ie, https://www.medicines.ie/ and http://www.orionproductsafety.com/ website.

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