Checklist for Community Pharmacists who dispense 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 dispensing 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 pharmacists who dispense or 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 (administered 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.

Communication points for community pharmacists when interacting with patient.

Counsel the patient on the use of the patient alert card (see further detail below).

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 Community Pharmacists

Actions to be taken	Completed
Conduct a patient review checking the following: • Indication for methotrexate prescribing. • Time period since last dispensing of methotrexate. • Occurrence of signs or symptoms of toxicity. • Change of medication • Dispensed medication history.	
Check that prescription includes the following dosage information: • Total dose. • Number of tablets to be taken weekly. • Frequency of dose stated as 'once weekly'. • Day of the week when the weekly dose should be taken. Only accept prescriptions for a once weekly dose within the usual dose range (usual dose range is 7.5mg – 25mg once weekly. Maximum dose is 30mg weekly).	
If the prescription does not include the dosage information query the prescriber and document the additional information.	
If the prescription states a more frequent dose than weekly **do not dispense**. Contact the prescriber and confirm the correct once weekly dose.	
Check for any dose changes since last prescription	
State on pharmacy label a day of the week (in full, no abbreviations) when the weekly dose should be taken, e.g. "Tuesday"	
Write on patient card a day of the week (in full, no abbreviations) when the weekly dose should be taken, e.g. "Tuesday"	
Remind patient/carer to always show the patient card to alert new healthcare professionals/carers about the once weekly dosing of methotrexate (e.g. on hospital admission, change of carer, etc.)	
Check that the patient/caregiver understands that the medicine must be taken once weekly only and highlight the risk of fatal intoxication	
Educate patients and their families/carers about the importance of adhering to the correct dose and frequency of administration.	
Educate patients and their families/carers on the signs and symptoms of intoxication and what action to take in the event of an overdose.	

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Patient Alert card

A patient alert card will be added to the outer package of methotrexate tablets. The card can be easily removed so that patient can 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 of the symptoms of toxicity and steps to be taken should symptoms arise
- Remind patients to show the card to 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 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 reaction 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

Further supplies of the checklist and patient alert card will be available in electronic format on www.hpra.ie, https://www.medicines.ie/ and www.orionproductsafety.com website.

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