■ Medical Safety Information
Pharmaceuticals and Medical Devices Agency
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No. 49 November 2016

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Precautions against Misuse (Overdose) of Antirheumatic Methotrexate Preparations (Part 2)

POINT Key points for safe use

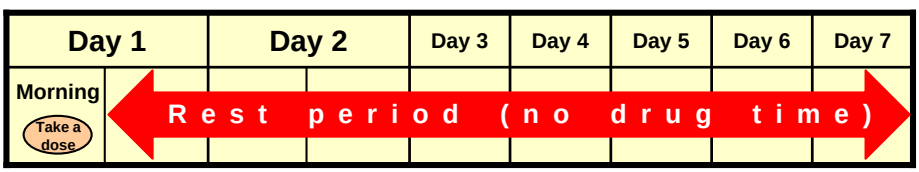
1 How to take antirheumatic methotrexate preparations

- **Methotrexate for treatment of rheumatoid arthritis is an oral drug with a special dosing regimen requiring rest period (drug is not taken).**

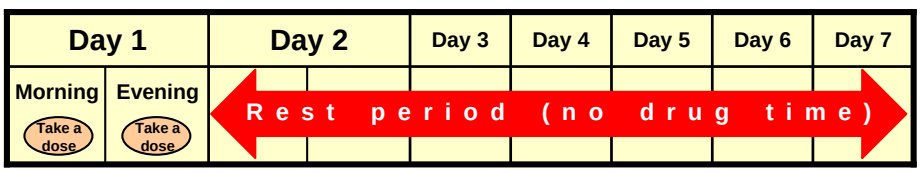
Dosing regimen

⚠ The same regimen applies to the use for juvenile “idiopathic arthritis with joint symptoms”. Please refer to the package inserts for dosage and administration.

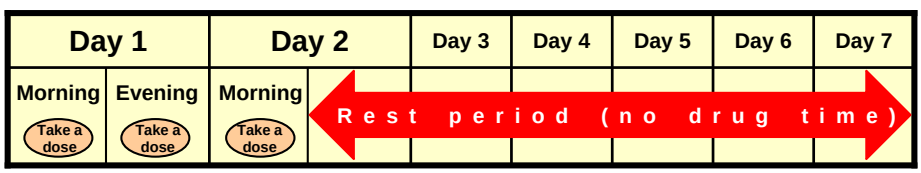
When taken once weekly



When taken twice weekly



When taken three times weekly



Repeat this dosing regimen every week

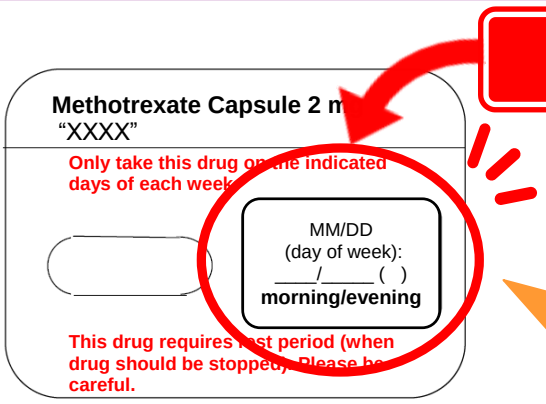
Taking methotrexate without a rest period by mistake may cause serious adverse reactions such as bone marrow depression!

2 Precautions on handling antirheumatic methotrexate preparations (1)

(Case) A patient with rheumatoid arthritis brought a methotrexate preparation on admission with no information on the date and time of dosing, and a nurse delivered the drug to the patient without a rest period.

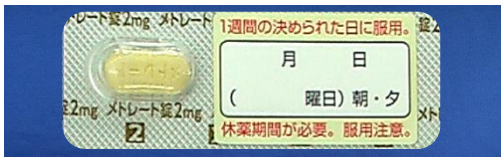
- **Date and time of dosing should be indicated in the specified field when the drug is dispensed and delivered.**

The dosing date and time are often not filled in, leading to countless cases of dosing errors. Check the patient's dosing schedule and fill in the dosing date and time.



If it is necessary to correct the dosing date or time, use the "correction sticker" provided by the company.

Ayumi Pharmaceutical Corp.



Metolate Tablets 2 mg

Pfizer Japan Inc.

Rheumatrex Capsules 2 mg

Mitsubishi Tanabe Pharma Corp.

Methotrexate Tablets 2mg "TANABE"

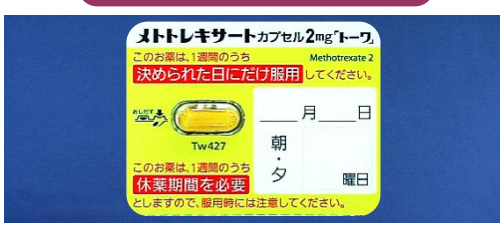
Sawai Pharmaceutical Co. Ltd.

Methotrexate Capsules 2mg "SAWAI"

Shiono Chemical Co. Ltd.

Methotrexate Capsules 2mg "SN"

Towa Pharmaceutical Co. Ltd.



Methotrexate Capsules 2 mg "TOWA"

Sandoz K.K.

Methotrexate Capsules 2 mg "SANDOZ"

3 Precautions on handling antirheumatic methotrexate preparations (2)

(Case) A rheumatoid arthritis patient who had taken a methotrexate preparation for several years decided, without consulting a healthcare professional, to take the unused methotrexate preparation that had been prescribed in the past, without a rest period.

- **Even patients who have been taking methotrexate preparations for many years may not have a correct understanding of the dosing regimen. Provide repeated instruction about the dosing regimen, as appropriate for the patient's level of understanding.**
- **Check the patient's adherence to dosing and the amount of unused medication, to prevent the misuse of unused medication.**

Additionally, make use of materials for preventing incorrect dosing that have been prepared by the companies providing methotrexate preparations.

<Example materials>

Dosing calendar

Stickers alerting patients about proper use

The Ministry of Health, Labour and Welfare (MHLW) issued notifications related to PMDA Medical Safety Information No. 49.

- Safety Division (SD), Pharmaceutical and Food Safety Bureau (PFSB) Notification 0829001 on August 29, 2008 "Preventive Measures against Medical Accidents regarding Misuse (Overdose) of Antirheumatic Methotrexate Preparations"
- Joint Notification of General Affairs Division (GAD), Health Policy Bureau (HPB) Notification 1020001, PFSB/GAD Notification 1020001, and PFSB/SD Notification 1020001 dated October 20, 2008 "Handling of Antirheumatic Methotrexate Preparations for Prevention of Misuse (Overdose) (precautions)"

These notifications are published on the Pharmaceuticals and Medical Devices Agency website (http://www.pmda.go.jp/) > Post-marketing Safety Measures > Information Services > Medical Safety Information > Medical Safety Measures for Pharmaceuticals and Medical Devices (only available in Japanese language).
You can also view information on the package inserts of the antirheumatic methotrexate preparations listed in this Medical Safety Information (http://www.pmda.go.jp/PmdaSearch/iyakuSearch/) (only available in Japanese language).

About this information

* **PMDA Medical Safety Information is issued by the Pharmaceuticals and Medical Devices Agency for the purpose of providing healthcare providers with clearer information from the perspective of promoting the safe use of pharmaceuticals and medical devices. The information presented here has been compiled, with the assistance of expert advice, from cases collected as Medical Accident Information Reports by the Japan Council for Quality Health Care, and collected as Adverse Drug Reaction and Malfunction Reports in accordance with the Pharmaceutical Affairs Law.**
* **We have tried to ensure the accuracy of this information at the time of its compilation but do not guarantee its accuracy in the future.**
* **This information is not intended to impose constraints on the discretion of healthcare professionals or to impose obligations and responsibility on them, but is provided as a support to promote the safe use of pharmaceuticals and medical devices by healthcare professionals.**

Access to the most up to date safety information is available via PMDA medi-navi.

Published by the Pharmaceuticals and Medical Devices Agency

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