

Drug Information Sheet("Kusuri-no-Shiori")

Internal
Revised: 03/2022

The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic response, patients should understand their medication and cooperate with the treatment.

Brand name: Methotrexate Tablets 2.5mg

Active ingredient: Methotrexate

Dosage form: pale yellow-brown tablet with split line, diameter: 6.4 mm, thickness: 3.1 mm

Print on wrapping: packed in a bottle, no printable sheets



Effects of this medicine

This medicine blocks the transformation of folic acid into its active forms and/or exerts cytostatic or cytotoxic action when taken up by normal cells or sensitive cancer cells.

It is usually used to treat acute leukemia, chronic lymphocytic leukemia, chronic myeloid leukemia or trophoblastic diseases (choriocarcinoma, invasive mole, hydatidiform mole).

Before using this medicine, be sure to tell your doctor and pharmacist

- If you have previously experienced any allergic reactions (itching, rash, etc.) to any medicines.
If you have: liver disorder, renal disorder, pleural effusion or ascites.
- If you are pregnant or breastfeeding.
- If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)

Dosing schedule (How to take this medicine)

- Your dosing schedule prescribed by your doctor is((to be written by a healthcare professional))
- For treatment of leukemia: In general, for adults, take a daily dose of 2 to 4 tablets (5 to 10 mg of the active ingredient), for children, a daily dose of 1 to 2 tablets (2.5 to 5 mg) and for infants, a daily dose of 1/2 to 1 tablet (1.25 to 2.5 mg), 3 to 6 days a week.
For treatment of trophoblastic disease: In general, for adults, take 4 to 12 tablets (10 to 30 mg of the active ingredient) per day, as 1 course for 5 days. The washout period is 7 to 12 days, and if any adverse reactions develop, treatment with this medicine should be withdrawn until the reactions disappear.
In any case, the dosage may be adjusted according to the age or symptoms. Strictly follow the instructions.
- If you miss a dose, skip the missed dose and follow your regular dosing schedule. You should never take two doses at one time.
- If you accidentally take more than your prescribed dose, consult with your doctor or pharmacist.
- Do not stop taking this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

- Do not receive live vaccines because use of live vaccines may intensify and continue the vaccine-derived infection during treatment with this medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include rash, hives, itching, fever and photosensitivity. If any of these symptoms occur, consult with your doctor or pharmacist.

The symptoms described below are rarely seen as initial symptoms of the adverse reactions indicated in brackets. If any of these symptoms occur, stop taking this medicine and see your doctor immediately.

- cold sense, respiratory distress, dropping blood pressure [shock, anaphylaxis]
- fever, sore throat, cold-like symptoms [myelosuppression]
- loss of appetite, general malaise, yellowing of the skin or the white of eyes [fulminant hepatitis, liver failure]
- decreased urine output, edema of face, dry mouth [acute renal disorder, tubular necrosis, severe nephropathy]
- fever, cough (dry cough), respiratory distress [interstitial pneumonia, pulmonary fibrosis, pleural effusion]

The above symptoms do not describe all the adverse reactions to this medicine. Consult with your doctor or pharmacist if you notice any symptoms of concern other than those listed above.

Storage conditions and other information

- Keep out of reach of children. Store away from light, heat and moisture.
- Discard the remainder. Do not store them. If you dispose of unused medicines, seek advice of your pharmacy or medical institution about proper disposal of the unused medicines.

For healthcare professional use only / /



For further information, talk to your doctor or pharmacist.