

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

Internal

Revised: 11/2022

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:**RHEUMATREX CAPSULES 2mg

**Active ingredient:**Methotrexate

**Dosage form:**yellow/yellow capsule, major axis: 14.7 mm, minor axis: 5.3 mm

**Imprint or print on wrapping:**リウマトレックスカプセル 2mg, Rheumatrex Capsules  
2mg, LL 606



**Effects of this medicine**

This medicine suppresses actions of lymphocytes in the immune system or of cells which relates to inflammation. It inhibits abnormal immune reaction to improve articular symptoms such as swelling and pain.

It is usually used to treat rheumatoid arthritis, plaque psoriasis with inadequate response to local therapy, psoriatic arthritis, pustular psoriasis, erythrodermic psoriasis and juvenile idiopathic arthritis with joint symptoms.

**The following patients may need to be careful when using this medicine. Be sure to tell your doctor and pharmacist.**

- If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines or foods.  
If you have: myelosuppression, chronic liver disease, renal disorder, pleural effusion, ascites, active tuberculosis (tuberculosis requiring treatment), hepatitis virus infection, infection, varicella (chickenpox), a history of tuberculosis or close contact with tuberculosis patient, lung disorder such as interstitial pneumonia and pulmonary fibrosis or its history.
- If you are pregnant, possibly 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 rheumatoid arthritis, plaque psoriasis with inadequate response to local therapy, psoriatic arthritis, pustular psoriasis, erythrodermic psoriasis: In general, take this medicine as a unit of one week (7 days). Weekly total dosage is 3 capsules (6 mg of the active ingredient), taken at once or in 2 to 3 divided doses. When dividing the dosage, take the dosage every 12 hours from day 1 to day 2. The remaining 6 days (when the dosage is taken at once or divided in 2 doses) or 5 days (when the dosage is divided in 3 doses) will be non-medication days. This course is repeated every week. The dosage may be adjusted according to the age, symptoms, tolerance and response to this medicine. However, the weekly dosage is up to 8 capsules (16 mg).  
For juvenile idiopathic arthritis with joint symptoms: In general, take this medicine as a unit of one week (7 days). Weekly total dosage is 4 to 10 mg of the active ingredient per square meter (/m<sup>2</sup>), taken at once or in 2 to 3 divided doses. When dividing the dosage, take the dosage every 12 hours from day 1 to day 2. The remaining 6 days (when the dosage is taken at once or divided in 2 doses) or 5 days (when the dosage is divided in 3 doses) will be non-medication days. This course is repeated every week. The dosage may be adjusted according to the age, symptoms, tolerance and response to this medicine.  
This preparation contains 2 mg of the active ingredient in a capsule.  
In any case, strictly follow the instructions.
- Take this medicine with a large amount of water. If you take this medicine right before bedtime, esophageal retention of this medicine may cause ulcer. Do not lie down right after taking this medicine.
- Before taking this medicine, the presence or absence of hepatitis virus infection is checked in blood tests. The presence or absence of lung disorder is also checked in examinations such as chest X-rays.
- If you miss a dose, skip the missed dose and follow your regular dosing schedule. A predetermined dose of this medicine should be taken at specified time on specified day of week. You should never take two doses at one time.
- If you accidentally take more than your prescribed dose, symptoms such as bleeding tendency, fever, malaise, nausea, abdominal pain and bloody stool may occur. Contact your doctor or pharmacist immediately.
- Do not stop taking this medicine unless your doctor instructs you to do so.

**Precautions while taking this medicine**

- This medicine is often taken for a long period of time and serious adverse reactions may occur during the treatment period. Receive an explanation to fully understand the necessity and precautions for the treatment.
- Serious adverse reactions such as myelosuppression and liver/renal dysfunction may occur. Before and while taking

this medicine, laboratory examinations (blood and liver/renal function tests, urinalysis, etc.) are usually performed every 4 weeks.

- Before taking this medicine, the presence or absence of tuberculosis infection is checked by interferon gamma release assay or tuberculin skin test in addition to medical interview and chest X-ray. Moreover, examinations such as chest X-ray are performed periodically while taking this medicine.
- Undergo the tests at specified dates and times.
- If symptoms suggestive of tuberculosis (prolonged cough, fever, etc.) occur, contact your doctor immediately.
- Hemorrhagic enteritis and gastrointestinal tract disorder such as gastrointestinal tract ulcer/bleeding may occur. If stomatitis or severe abdominal pain occurs, contact your doctor immediately.
- Infection and bleeding tendency may occur. If fever or malaise occurs, contact your doctor immediately.
- This medicine may make you susceptible to infections. Try to adopt preventive measures against infections, such as avoiding crowded spaces and washing hands and gargling the throat after going out.
- If you drink alcohol every day, inform your doctor or pharmacist of it before taking this medicine, since liver disorder may worsen.
- Since several cases of possible teratogenicity have been reported, female patients with a possibility of getting pregnant should avoid pregnancy during medication and at least for one menstrual cycle after discontinuation of this medicine.  
Male patients should be careful so that his partner does not become pregnant during medication and at least for 3 months after discontinuation of this medicine.

### **Possible adverse reactions to this medicine**

The most commonly reported adverse reactions include liver dysfunction, rash, itch, fever, bloody urine, proteinuria (cloudy urine), nausea, abdominal pain, diarrhea, stomatitis, loss of appetite, vomiting, glossitis, alopecia, headache, dizziness, cough, dyspnea, malaise, palpitation, pressure in chest and edema. 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 feeling, dyspnea, decreased blood pressure [shock, anaphylaxis]
- fever, sore throat, cold-like symptoms [myelosuppression]
- loss of appetite, general malaise, yellowing of the skin and the white of eyes [fulminant hepatitis, liver failure]
- decreased urine output, edema of face, etc., dry mouth [acute renal disorder, tubular necrosis, severe nephropathy]
- fever, cough (dry cough), dyspnea [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 at room temperature (1 to 30 degrees Celsius), away from direct sunlight and moisture.
- Discard the remainder. Do not store them. If you do not know how to dispose of the unused medicines, seek advice of your pharmacy or medical institution. Do not give the unused medicines to others.
- Do not receive live vaccines (rubella, mumps, chickenpox, measles and BCG, etc.) while taking this medicine. Use of live vaccines may intensify or continue the vaccine-derived infections. If you wish to receive live vaccines, consult with your doctor.

**For healthcare professional use only** / /

For further information, talk to your doctor or pharmacist.