METHOTREXATE
2.5 mg Tablets

Dear patient,
Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about METHOTREXATE
Each METHOTREXATE tablet contains 2.5 mg methotrexate.
Methotrexate is an antimetabolite of folic acid. It also has immunosuppressant properties. Methotrexate inhibits dihydrofolate reductase, an enzyme necessary for the formation of DNA the genetic material in the cells.
Methotrexate is used in the following cases:
- Symptomatic control of severe, recalcitrant, disabling psoriasis that is not adequately responsive to other forms of therapy
- Management of selected adults with severe, active rheumatoid arthritis; early treatment with methotrexate helps reducing further joint damage and preserving joint function
- Management of selected children with active polyarticular-course juvenile arthritis
- Treatment of certain neoplastic diseases
Methotrexate may be used for the treatment of other disorders such as lupus, Crohn's disease and psoriatic arthritis.

The way to take METHOTREXATE
Take METHOTREXATE as directed by your physician. Do not discontinue the treatment or change the dosage prescribed without consulting your doctor. Dosage and duration of treatment are individualized according to the disease process. An initial test dose may be given prior to the regular dosing schedule to detect any extreme sensitivity to adverse effects.
The recommended starting dosage schedules are:

Indications	Starting Dosage
Adult rheumatoid arthritis	Single oral doses of 7.5 mg once weekly (3 tablets of 2.5 mg once weekly) or
	Divided oral dosage of 2.5 mg (1 tablet) at 12-hour intervals for three doses given as a course once weekly
Polyarticular-course juvenile rheumatoid arthritis	10 mg/m² once weekly
Psoriasis	Weekly single oral schedule: 10 mg to 25 mg (4 to 10 tablets of 2.5 mg) once per week until adequate response is obtained or
	Divided oral dose schedule: 2.5 mg (1 tablet) at 12-hour intervals for three doses as a course once weekly

- Dosages in each schedule may be gradually adjusted to achieve optimal clinical response. After an optimal response to the drug is achieved, each schedule should be reduced to the lowest possible dose.
Maximum dose in adult rheumatoid arthritis is 20 mg/week.
Maximum dose in psoriasis is 30 mg/week.
- Various dosage schedules are available for cancer therapy
Methotrexate may be used alone or in combination with other antineoplastic agents and/or radiation therapy.
Dosage and duration of therapy are individualized according to the disease being treated, other therapy being employed, and the condition, response, and tolerance of the patient.

In case of overdose
In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted. Leucovorin (calcium folinate) is indicated to diminish the toxicity and counteract the effect of methotrexate.

In case of missed dose
Contact your doctor if you miss a dose of methotrexate.

Contraindications
This drug is contraindicated in the following conditions:
- Known hypersensitivity to any of the components
- Pregnancy and lactation
- Patients with alcoholism, alcoholic liver disease or other chronic liver disease
- Immunodeficiency syndromes
- Preexisting blood disorders such as leucopenia, or significant anemia
- Severe renal impairment
- Chronic respiratory failure

Precautions
- Complete blood counts, tests of renal and liver function, chest X-ray, and gastrointestinal monitoring should be performed before starting therapy and periodically thereafter.
- Pregnancy should be excluded before starting therapy. Pregnancy should be avoided if either partner is receiving this drug; during and for a minimum of three months after therapy for male patients, and during and for at least one ovulatory cycle after therapy for female patients.
- Periodic liver biopsies are usually recommended for psoriatic patients who are under long-term treatment.
- Inform your doctor at once in case of unexplained dry, nonproductive cough, dyspnea, diarrhea, vomiting, stomatitis, skin reactions, pneumonia, fever, significant drop in blood counts, or any symptoms or signs suggestive of infection, especially sore throat.
- It is recommended to remain under close medical follow-up throughout therapy.
- The recommended dose is taken weekly in rheumatoid arthritis and psoriasis. Mistaken daily use of the recommended dose may lead to fatal toxicity.
- This drug should be used with great care in patients with bone-marrow, hepatic or renal impairment; in case of peptic ulcer disease, ulcerative colitis, pleural or ascetic effusions, active infection; and in the elderly, debilitated patients and the very young patients.
- Lesions of psoriasis may be aggravated by concomitant exposure to ultraviolet radiation.
- Avoid prolonged exposure to sunlight during treatment.

Associations with other medications
Please inform your doctor if other medicines are being taken or have been taken recently.
Avoid alcoholic beverages during treatment with this medication.
Caution should be used when administered concomitantly with NSAIDs, salicylates, phenylbutazone, phenytoin, sulfonamides, probenecid, cisplatin, cytotoxic agents, vaccines, oral anticoagulants, cyclosporine, penicillins, tetracycline, chloramphenicol, nonabsorbable broad spectrum antibiotics, azathioprine, retinoids, sulfasalazine, theophylline, trimethoprime and sulfamethoxazole.

Adverse reactions
In general, the incidence and severity of acute side effects are related to dose and frequency of administration.
Most adverse reactions are reversible if detected early.
The most reported adverse reactions include ulcerative stomatitis, leucopenia, nausea, vomiting, abdominal distress, malaise, fatigue, chills and fever, dizziness, decreased resistance to infection, elevated liver function tests, blood disorders, and allergic reactions.
Rarely reported adverse reactions include headache, upper respiratory infection, anorexia, chest pain, cough, eye discomfort, vaginal discharge or photosensitivity.
Other side effects than those listed may also occur. Please inform your doctor promptly if any side effect appears or becomes bothersome.

Storage
Store at controlled room temperature (up to 25°C), protected from light and humidity, beyond the reach of children.
The expiry date is printed on the pack; don't use this medicine after this date.

Pack Presentation
METHOTREXATE 2.5 mg, pack of 100 tablets

Revision date: 05/2006
METT25/004

For further information, visit our company's web site: www.medipharlabs.com or call the "Consumer Healthcare Service" at 961-4-542821.