

PFZ METHOTREXATE[®] TABLET

Methotrexate (2.5 mg)

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What METHOTREXATE is used for

METHOTREXATE is used alone or in combination with other anticancer agents to treat various cancers. METHOTREXATE is also indicated in the symptomatic control of severe psoriasis when other treatments are not responsive.

METHOTREXATE can also be used for the treatment of Rheumatoid arthritis (RA) in adults.

How METHOTREXATE works

METHOTREXATE works by blocking an enzyme process in cells that is required for cell growth. This interferes with the growth of some cells that are growing rapidly in psoriasis or rheumatoid arthritis and cancer.

The precise mechanism of METHOTREXATE in treating rheumatoid arthritis is uncertain. METHOTREXATE is either taken alone or with other medicines. METHOTREXATE is considered as a disease-modifying anti-rheumatic drug (DMARD) for the treatment of rheumatoid arthritis.

Before you use METHOTREXATE

- When you must not use it

Do not take METHOTREXATE:

- if you are allergic to METHOTREXATE or to any other ingredients used in this medicine
- if you have severe kidney problems
- if you are breast feeding

Do not take METHOTREXATE for treatment of psoriasis or rheumatoid arthritis if:

- you consume excessive amounts of alcohol
- you have long-term liver problems
- you have severely compromised immune system
- you have blood problems like insufficient activity of bone marrow and reduced number of red or white blood cells or platelets
- you are pregnant or planning to become pregnant

Pregnancy and lactation

Do not take METHOTREXATE if you are pregnant, trying to get pregnant or think you may be pregnant. Pregnancy should be avoided if either partner is receiving METHOTREXATE.

METHOTREXATE can cause fetal death, abortion or birth defects to your baby. Before starting treatment, your doctor will do a pregnancy test and discuss the risks to fetus if you become pregnant while using this medicine.

METHOTREXATE passes into breast milk. Do not take METHOTREXATE if you are breastfeeding.

Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Before starting the treatment, your

doctor will inform you the risks involved and you will be under physician's constant supervision. Tell your doctor if you have or have had any of the following conditions:

- kidney problems
- active infections
- liver problems, including hepatitis B or hepatitis C
- folate deficiency
- excess fluid in lungs or abdomen
- obesity
- diabetes
- stomach or intestinal blockage
- previous cisplatin therapy
- ulcer or inflammation in the bowel
- undergoing radiotherapy
- are receiving or intend to receive any vaccine
- dehydration
- abnormal amounts of acid in urine

Skin reactions, including dermatitis, sensitivity or increased sunburn have been observed after taking METHOTREXATE. You should avoid intense sunlight or UV rays and use adequate sun-protection.

Before starting the treatment, your doctor will take blood samples to check your blood values and how your liver, kidneys and lungs function. Blood samples will be regularly taken even during the treatment.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

You can continue taking non-steroidal anti-inflammatory drugs (NSAIDs), aspirin and/or steroids at low doses along with METHOTREXATE in the

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treatment of rheumatoid arthritis.

It is particularly important to tell your doctor if you are taking any of the following medicines:

- Cisplatin, cytarabine, L-asparaginase, mercaptopurine (anticancer medicines)
- Disease modifying antirheumatic drug (DMARD)
- Non-steroidal anti-inflammatory drugs (NSAIDs)
- Proton pump inhibitors (heartburn medicines)
- Ciprofloxacin, penicillin, tetracycline, chloramphenicol trimethoprim/sulfamethoxazole, pristinamycin, sulphonamide (antibiotics)
- Pyrimethamine (anti-malaria)
- Leflunomide, azathioprine, sulfasalazine, retinoids, metamizole (medicines that cause liver toxicity)
- Nitrous oxide anesthesia
- Probenecid (antigout medication)
- Vitamin products that contain folic acid or similar ingredients
- Amiodarone (medicine for irregular heart beat)
- Sulfonylureas, aminobenzoic acid, salicylates, phenylbutazone, phenytoin
- Methoxsalen (a medicine used with ultraviolet light in PUVA therapy for conditions such as severe psoriasis)
- Theophylline (an asthma medicine)
- Triamterene (water pill)

How to use METHOTREXATE

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Your doctor will tell you how much METHOTREXATE to take and when to take it. Do not change your

dose of METHOTREXATE unless your doctor tells you to do so.

The dose of medicine given to you will depend on the disease being treated and your medical condition. You can refer to your healthcare professional for more information.

Use in Children

Safety and effectiveness in children have been established only in cancer treatment.

Use in Elderly

Elderly should take the recommended lower dose weekly for psoriasis or rheumatoid arthritis.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking METHOTREXATE for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may

need urgent medical attention.

Symptoms of overdose may include decrease in different types of blood cells, nausea, vomiting, ulcers and bleeding in the stomach and intestine. In serious cases, overdose may even lead to kidney failure and death.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking METHOTREXATE.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give METHOTREXATE to anyone else, even if they have the same symptoms or condition as you.

METHOTREXATE tablet should not be broken.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, do not drive or use machines and contact your doctor immediately.

Fertility

Treatment with METHOTREXATE may reduce

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fertility in men and women. Tell your doctor if you have concerns.

Side effects

Like all medicines, METHOTREXATE can cause side effects, although not everybody gets them.

Tell your doctor or pharmacist if you experience any side effects after taking METHOTREXATE.

Most frequently reported side effects with METHOTREXATE include:

- Painful mouth ulcers
- Decrease in the number of white blood cells
- Nausea
- Stomach discomfort
- A general feeling of discomfort, illness, or unease
- Tiredness
- Chills
- Fever
- Dizziness
- Decreased resistance to infection

Common side effects with METHOTREXATE include:

- Burning or prickling sensation (paresthesia).

If you get symptoms like dry non-productive cough, fever, chest pain or breathing difficulty, inform your doctor immediately as METHOTREXATE can cause serious lung diseases.

If diarrhoea or severe vomiting causing dehydration occurs during treatment, your doctor may stop the medicine and start supportive therapy.

Tell your doctor if you have any side effects that bother you or that does not go away.

These are not all of the possible side effects of METHOTREXATE. For more information ask your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nptra.gov.my [Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of METHOTREXATE

- Storage

Store at room temperature below 30°C. Protect from light.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Procedures for proper handling and disposal of anticancer drugs should be considered. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

METHOTREXATE 2.5 mg tablets are round, convex, yellow in colour, approximately 6.35 ± 0.1 mm in diameter, engraved with '2.5' on one side and scored in half on the other side and engraved with a block letter 'M' above the score and 'I' below.

- Ingredients

Active ingredient

Methotrexate

Inactive ingredients

Magnesium Stearate
Sodium Hydroxide
Pregelatinised Maize Starch
Lactose Monohydrate
Purified Water

- MAL number:

MAL20000041ACZ

Manufacturer and Packager

Excella GmbH & Co. KG
Nuernberger Strasse 12,
90537 Feucht, Germany

Product Registration Holder

Pfizer (Malaysia) Sdn. Bhd.
Level 10 & 11.
Wisma Averis, Tower 2,
Avenue 5, Bangsar South,
No. 8 Jalan Kerinchi,
59200 Kuala Lumpur, Malaysia

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