

FINAL APPROVED PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any questions, consult your doctor, pharmacist or other health care professional for advice.
- This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

SCHEDULING STATUS:

S4

NAME, STRENGTH AND DOSAGE FORM

METHOTREXATE*-Lederle 2,5 Tablets

1. WHAT METHOTREXATE*- LEDERLE 2,5 CONTAINS

METHOTREXATE*-Lederle 2,5 Tablets: Contain 2,5 mg of methotrexate.

WARNING

DO NOT TAKE METHOTREXATE EVERY DAY.

Check with your doctor, nurse or pharmacist if you are not sure about how much and how often to take this medicine. In some cases your doctor, nurse or pharmacist may give special directions on how to take your METHOTREXATE*- LEDERLE 2,5

2. WHAT METHOTREXATE*- LEDERLE 2,5 IS USED FOR

METHOTREXATE*-LEDERLE 2,5 belongs to a group of medications called antifolates. At lower doses, It is used to treat severe rheumatoid arthritis and psoriasis. It may also be used at higher doses to treat many types of cancers. METHOTREXATE*-LEDERLE 2,5 is used to treat many types of cancers in adults and children. These include breast cancer, non-Hodgkin's lymphoma and leukaemia.

METHOTREXATE*-LEDERLE 2,5 works by blocking an enzyme needed by body cells to live. This interferes with the growth of some cells, such as skin cells in psoriasis that are growing rapidly. In rheumatoid arthritis, METHOTREXATE*-LEDERLE 2,5 acts on the inflammatory cells which cause joint swelling.

METHOTREXATE*-LEDERLE 2,5 is used to control psoriasis and rheumatoid arthritis but it will not cure them. In cancer, METHOTREXATE*-LEDERLE 2,5 works by blocking an enzyme process in cancer cells so that they cannot grow. Some normal cells in the body may be affected as well.

Your doctor may have prescribed METHOTREXATE*-LEDERLE 2,5 for another purpose. Ask your doctor if you have any questions about why it has been prescribed for you.

This medicine is only available with a doctor's prescription.

3. BEFORE YOU ARE GIVEN METHOTREXATE*-LEDERLE 2,5

Before you start taking this medicine, you should talk to your healthcare professional about the risks and benefits of using METHOTREXATE*-LEDERLE 2,5. It is very important that you take METHOTREXATE*-LEDERLE 2,5 exactly as recommended by your healthcare professional. If METHOTREXATE*-LEDERLE 2,5 is taken more frequently or in larger doses than prescribed, serious illness, including death can occur.

➤ *Do not take METHOTREXATE*-LEDERLE 2,5*

- if you are allergic (hypersensitive) to METHOTREXATE*-LEDERLE 2,5 or any of the other ingredients in the formulation.
- if you are breast-feeding or if you intend to breast-feed.
- if you are pregnant or intend to become pregnant.

METHOTREXATE*-LEDERLE 2,5 may cause birth defects if either the male or female is taking it before, during, or after pregnancy. Both men and women must use effective birth control all the time while taking METHOTREXATE*-LEDERLE 2,5 and after they stop taking it. Consult your health care professional if you become pregnant or wish to become pregnant.

Applies to patients with psoriasis or rheumatoid arthritis only:

➤ *Do not take METHOTREXATE*-LEDERLE 2,5*

- if you suffer from alcoholism, alcoholic liver disease, or other chronic liver disease.
- if you have a disorder of the immune system, such as AIDS.
- if you have preexisting blood diseases (you must discuss this with your healthcare professional).

➤ *Take special care with METHOTREXATE*-LEDERLE 2,5 and notify your healthcare professional immediately.*

- if you have serious infections or skin reactions.
- if you develop cough or shortness of breath.
- if you are exposed to chicken pox or shingles and have not had these diseases in the past.
- if you notice unusual bleeding or bruising, blood in urine or stools, or red spots on your skin.
- if you are taking vaccines. Certain vaccines may not work well while you are on METHOTREXATE*-LEDERLE 2,5 and "live" virus vaccines should be avoided; discuss this with your healthcare professional.

METHOTREXATE*-LEDERLE 2,5 may make your skin sensitive to the sun, so avoid long exposure to the sun and do not use a sunlamp without first discussing its use with your healthcare professional.

➤ *Taking other medicines.*

Please tell your healthcare professional if you are taking or have recently taken any other medicines, including herbal preparations and vitamins, since some medications interact with METHOTREXATE*-LEDERLE 2,5, including anti-inflammatory drugs such as ibuprofen or aspirin, some antibiotics, theophylline, phenytoin, and probenecid.

Other drugs that affect the liver may increase the chance of liver problems with METHOTREXATE*-LEDERLE 2,5. These medications include leflunomide, azathioprine, sulfasalazine and retinoids.

➤ *Taking METHOTREXATE*-LEDERLE 2,5 with food and drink*

While taking METHOTREXATE*-LEDERLE 2,5 you should avoid drinking alcohol, since this may increase the chance of side effects, especially on the liver. Your healthcare professional may tell you to drink extra fluids. This will help the drug to pass from the body and to prevent kidney problems.

➤ *Driving and using machines*

Dizziness and fatigue may occur and affect your ability to drive or operate machinery.

➤ *Other important information*

METHOTREXATE*-LEDERLE 2,5 can lower the number of blood cells responsible for fighting infections and for proper blood clotting. Notify your healthcare professional immediately if you get a fever, chills, cough, lower back or side pain, painful urination or unusual bleeding.

4. HOW TO USE METHOTREXATE*-LEDERLE 2,5

- Take METHOTREXATE*-LEDERLE 2,5 exactly as prescribed by your doctor. Your dose of METHOTREXATE*-LEDERLE 2,5 and when you take it will depend on the condition that is being treated. Do not take more METHOTREXATE*-LEDERLE 2,5 than prescribed. Do not change your dose unless your doctor has told you to.

The exact amount of METHOTREXATE*-LEDERLE 2,5 you need has been carefully determined. You should check with your doctor, nurse if you are not certain how to take the medication.

- In most cases, METHOTREXATE*-LEDERLE 2,5 is taken once weekly; the prescribed dose is taken on a single day of the week.

- In some cases, your doctor may instruct you to take METHOTREXATE*-LEDERLE 2,5 every 12 hours for 3 doses; you should only do this once a week, and should not take more than 3 doses each week.

- It should never be taken every day of the week.

- Taking METHOTREXATE*-LEDERLE 2,5 daily, or in a dose larger than prescribed can result in serious complications, often requiring hospitalization, and sometimes resulting in death. Taking even small doses of METHOTREXATE*-LEDERLE 2,5 daily for less than a week can result in serious consequences, including death.

- Select a day of the week when you are most likely to remember to take METHOTREXATE*-LEDERLE 2,5 and take it on that same day each week.

- Each time you refill your prescription, check to see whether the dose and/or the number of tablets you need to take have changed.

METHOTREXATE*-LEDERLE 2,5 is used in high doses to treat many types of cancers. At lower doses, it may also be used to treat psoriasis and rheumatoid arthritis.

Psoriasis and Rheumatoid Arthritis:

The starting dose is usually 7,5 mg (3 tablets) taken on the same day each week. METHOTREXATE*-LEDERLE 2,5 is taken once a week either as a single dose or in three doses over a 24 or 36-hour period. Your doctor may increase the dosage after 6 weeks if necessary.

Take this medicine only as directed by your doctor or pharmacist if their advice is different from this.

Cancer:

Ask your doctor to explain the treatment course with you.

The dose is tailored to each patient's body size, age and disease.

Keep all appointments for the treatments and the blood tests.

Regular blood tests will be taken to plan your further treatments.

If you miss an appointment or dose, let your doctor know as soon as possible.

How long to take METHOTREXATE*-LEDERLE 2,5:

For treatment of both psoriasis and rheumatoid arthritis, treatment with METHOTREXATE*-LEDERLE 2,5 is long-term. You may need to take it for a number of years. Your doctor may reduce the dose if the disease is in remission and may increase the dose at times of disease flare-up. For patients with psoriasis. It will generally be possible to stop taking it until the next flare-up.

For the treatment of cancer, the dosage and frequency of METHOTREXATE*-LEDERLE 2,5 treatment depends on the type of cancer. It will generally be given each day for a number of days, followed by a break, and then the cycle of treatment will start again. It is generally part of a combination therapy given in cycles.

Things you must not do:

Do not take METHOTREXATE*-LEDERLE 2,5 every day of the week. Make sure you take the correct dose once a week, or in divided doses over a 36-hour period, once each week.

Some patients with psoriasis may be advised to take it in divided doses over 24 hours, once each week.

Do not let anyone else handle the tablets.

If you forget to take the tablets:

If you forget a dose, take it within 24 hours of the scheduled day; if there is a longer delay, check with your healthcare professional before taking it. Do not take a double dose to make up for a forgotten dose.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, then contact your doctor for advice on when to take the next dose.

5. POSSIBLE SIDE EFFECTS

Like all medicines, METHOTREXATE*-LEDERLE 2,5 can cause side effects, although not everybody gets them. Some of these side effects may result in death. There is a chance that METHOTREXATE*-LEDERLE 2,5 might cause side effects that may not occur until months or years after use because of the way METHOTREXATE*-LEDERLE 2,5 acts on your body. These delayed effects may include certain types of cancers. Discuss this with your doctor or pharmacist.

METHOTREXATE*-LEDERLE 2,5 can cause serious and life-threatening problems including:

- birth defects and death of the unborn child
- serious anaemia, lower white cells, red cells, and platelets in your blood
- damage to kidneys, liver, heart, bones or nervous system
- ulcers in the mouth, throat, or intestines
- severe skin reactions
- diabetes
- inflammation of the blood vessels
- change in mood
- seizures
- change in vision including temporary blindness
- low blood pressure
- lung disease
- cancer of the lymph system (lymphoma)
- severe skin reactions and rashes
- opportunistic infections such as *Pneumocystis carini* pneumonia
- soft tissue and bone damage if you are getting radiation therapy at the same time you are taking

METHOTREXATE*-LEDERLE 2,5

The most common side-effects of METHOTREXATE*-LEDERLE 2,5 include:

- mouth sores
- low white blood cells
- nausea, upset stomach
- feeling poorly
- unusual weakness or tiredness, chills, fever or cough, dizziness
- higher chance for getting infections
- diarrhoea, vomiting, abdominal pain
- hair loss
- easy bruising
- yellow colour of eyes or skin
- rash
- bleeding
- severe headache

Stop taking METHOTREXATE*-LEDERLE 2,5 _ and call your doctor immediately if you get diarrhoea, mouth sores, a fever, dehydration, cough, bleeding, shortness of breath, any signs of infection, or a skin rash. If you have any questions about these or other side-effects, talk to your doctor.

These are not all the side-effects of METHOTREXATE*-LEDERLE 2,5. Ask you doctor or pharmacist for more information.

Not all side effects reported for this medicine are included in this leaflet. If you notice any other side effects not mentioned in this leaflet, please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF METHOTREXATE*-LEDERLE 2,5

Store at or below 25°C. The tablets should be stored in the original packaging which prevents access of moisture and protected from light.

Do not handle METHOTREXATE*-LEDERLE 2,5 if you are pregnant or intend to become pregnant.

Do not use METHOTREXATE*-LEDERLE 2,5 after the expiry date that is stated on the label, carton, or bottle. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Store all medicines out of reach of children.

7. PRESENTATION OF METHOTREXATE*-LEDERLE 2,5

Tablets packed in opaque, white PVC/Al blisters in a pack size of 100 tablets

8. IDENTIFICATION OF METHOTREXATE*- LEDERLE 2,5

METHOTREXATE*-LEDERLE 2,5 Tablets:

Round, convex, yellow, tablets which may be mottled, 6,4 mm in diameter; engraved with script "2.5" on the one side, scored in half on the other side and engraved with a block letter "M" above the score and "1" below.

9. REGISTRATION NUMBER

Ref. No. H2766 (Act 101/1965)

10. NAME AND BUSINESS ADDRESS OF REGISTRATION HOLDER

Pfizer Laboratories (Pty) Ltd
85 Bute Lane
Sandton
2196

11. DATE OF PUBLICATION

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