

Core CMI for Methotrexate (text in italics is instructional for the CMI writer only)

[Medicine name][®]

(If you want to include phonetic spelling, the Second Edition of the Usability Guidelines suggests using the system outlined in the Webster's International Dictionary).

Methotrexate

Consumer Medicine Information

Date of Dispensing

Consumer Name

Pharmacist Name

Consumer Address

Pharmacist Address

Consumer Address

Pharmacist Address

What is in this leaflet¹

This leaflet answers some common questions about [Medicine name].

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

The medicine contains methotrexate, which belongs to a family of medicines called antimetabolites. It may also be called a chemotherapy medicine.

The medicine works by blocking an enzyme needed by the body cells to live. This interferes with the growth of some cells that are growing rapidly in psoriasis and cancer. In rheumatoid arthritis, this medicine reduces the overactivity of the immune system leading to less pain, swelling and damage to the joints.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

It is only available with a doctor's prescription.

What [Medicine name] is used for

It may be useful to include subheadings for 'psoriasis', 'rheumatoid arthritis' and 'cancer'.

This medicine is used to treat:

- severe psoriasis (a skin condition)
- severe rheumatoid arthritis (a chronic inflammatory condition)
- some types of cancers.

Before you take [Medicine name]

When you must not take it

Include all Contraindications that appear in the PI (examples below)

Do not take the medicine if you have an allergy to:

- any medicine containing methotrexate

- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.
- (add any other specific reactions listed in the PI).

Do not take the medicine if you have:

- severe kidney problems
- lowered immunity due to diseases such as HIV/AIDS or due to other treatments
- blood disorders, including anaemia (low iron in the blood) and reduced number of red or white blood cells or platelets
- bone marrow disease
- liver disease
- stomach ulcers
- ulcerative colitis, inflammation of the bowel
- an infection
- an alcohol dependence (alcoholism)

Do not take the medicine if you are pregnant or trying to become pregnant.

Do not take the medicine if your partner is trying to become pregnant.

¹ Depending on the length of the CMI, consider using a table of contents (see Second Edition of the Usability Guidelines)

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The medicine may cause birth defects if either you or your partner is taking it.

Do not take the medicine if you are breastfeeding.

It passes into the breast milk and may affect you baby.

Do not take this medicine if you are taking acitretin or e-tretinate, a medicine used to treat psoriasis and other skin conditions.

Any other contraindications, as per PI.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor .

Before you start to take it

Include all relevant information from the Precautions section of the PI (examples below). Do not duplicate any information from the previous section, unless necessary.

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- kidney problems
- lung problems
- diabetes
- folate deficiency
- *Other medical conditions as per the PI*

Your doctor may do tests to check your blood, liver and kidneys.

Tell your doctor if you have an infection or high temperature.

Your doctor may decide to delay your treatment until the infection has gone. A mild illness, such as a cold, is not usually a reason to delay treatment.

Tell your doctor if you or your partner becomes pregnant while

you are taking or just after you stop taking the medicine.

The medicine may cause birth defects if either the male or female partner is taking it. Use a proven method of birth control, such as the contraceptive pill or a condom, while taking the medicine and for at least 12 weeks after you stop treatment.

Any other precautions, as per PI.

If you have not told your doctor about any of the above, tell them before you start using the medicine.

Taking other medicines

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

Do not take folic acid on the same day as methotrexate.

Folic acid is included in many multi-vitamin preparations. Folic acid and methotrexate interact with each other if you take them on the same day of the week. It is all right to take these medicines on another day of the week.

Some other medicines and methotrexate may interfere with each other. These include:

- aspirin and other pain relievers or anti-inflammatory medicines
- some antibiotics
- phenytoin, a medicine used to treat epilepsy
- sulfonylurea medicines used to treat diabetes
- probenecid, medicines used to treat gout
- pyrimethamine, a medicine used to prevent malaria
- cholestyramine, a medicine used to lower blood cholesterol levels
- theophylline, a medicine used to treat asthma
- azathioprine, a medicine used to prevent transplant organ rejection

- amiodarone, a medicine used to treat heart disorders
- leflunomide, a medicine used to treat rheumatoid arthritis
- sulfasalazine, a medicine used to treat Crohn's disease, ulcerative colitis and rheumatoid arthritis
- retinoids (e.g. acitretin or e-tretinate), medicines used to treat skin conditions
- some medicines used to treat cancers
- methoxsalen, a medicine used with UV light for skin conditions, such as severe psoriasis
- vaccines
- nitrous oxide anaesthesia
- *Other medicines as noted in the PI*

Tell your doctor if you drink alcohol.

Alcohol may affect how well the methotrexate works. Your doctor has more information on medicines to be careful with or avoid while using this medicine.

Talk to your doctor if you are not sure whether you should be taking this medicine.

How to take [Medicine name]

Important Dosage Instructions

Always read the pharmacist's label to check the exact dose and how often to take it.

The dose depends on the condition this medicine is being used for.

Make sure that you understand how often your doctor wants you to take methotrexate to treat your medical condition.

There are different doses for rheumatoid arthritis or psoriasis, and cancer. It is important not to take methotrexate more often or in higher doses than your doctor has prescribed for your condition.

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Overdoses of methotrexate may cause serious illness or death.

If you are unsure about the dosage, ask your doctor or pharmacist.

Never take it more often than your doctor has told you to.

Your doctor will tell you how much to take and when to take it.

How to take it

Do not crush or chew the tablets.

Swallow the tablets whole with a full glass of water.

Rheumatoid arthritis and psoriasis

Take the tablets once a week on the same day each week for rheumatoid arthritis and psoriasis.

Only take your dose on the day agreed with your doctor or pharmacist.

Cancer

For cancer, take the tablets at the same time of day and only on the days specified by your doctor.

Taking the tablets at the same time of day will have the best effect. It will also help you to remember when to take the medicine.

How long to take it

Continue taking the medicine for as long as your doctor tells you to.

Ask your doctor if you are not sure how long to take it.

If you forget to take it

If you forget to take a dose, ask your doctor or pharmacist for advice.

Never take a double dose to make up for the dose that you missed.

If you find it hard to remember how to take the tablets, ask your doctor or pharmacist for help.

If you use too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 131 126), or go to accident and emergency at your nearest hospital, if you think you or anyone else may have taken too much [Medicine name]. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking [Medicine name]**Things you must do**

Tell your doctor or pharmacists if you are taking any other medicines.

Check your tablets very carefully each time you collect them from your pharmacist.

Methotrexate tablets are made in two strengths. You should check to make sure that you are given the correct strength. *(Only companies that supply 2 strengths to add this statement)*

Wash your hands immediately after taking the medicine.

Drink plenty of water on the day you take the medicine.

The recommended daily intake is 8 glasses per day.

Keep all of your doctor's appointments so that your progress can be checked.

You will need to have regular blood and urine tests. Regular blood tests will show any abnormal effects of methotrexate on the blood cells and the liver. As you may not get symptoms of these problems you must have regular blood checks. Your doctor may also want you to have some other tests.

Use a proven method of birth control, such as the contraceptive pill or a condom, while taking the

medicine and for at least 12 weeks after stopping treatment.

The medicine may cause birth defects if either you or your partner is taking it.

If you become pregnant while using this medicine, tell your doctor immediately.

Tell any other doctors, dentists, or pharmacists who treat you that you are taking this medicine.

If you are about to be started on any new medicine, remind your doctor, dentist or pharmacist that you are taking this medicine.

If you are going to have surgery, tell the surgeon, anaesthetist or dentist that you are using this medicine.

It may affect other medicines used during surgery.

Things you must not do

Do not go out in the sun if possible.

If you need to be in the sun, use a 30+ sunscreen and wear a hat and shirt to protect your skin from the sun.

This medicine may make your skin more sensitive to sunlight. This means your skin may burn more quickly than usual. Some signs are:

- redness
- itching
- swelling
- blistering
- rash.

Do not use sun lamps.

Do not drink alcohol while taking the medicine.

Alcohol may increase the side effects of the medicine.

Do not stop taking the medicine, or change the dose, unless your doctor tells you to.

Do not start to take any other medicine before talking to your doctor or pharmacist.

Do not use this medicine to treat any other conditions unless your doctor tells you to.

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Do not allow pregnant women to handle this medicine.

Do not give your medicine to anyone else, even if they have the same condition as you.

Any other instructions, as per PI.

Things to be careful of

Be careful driving or operating machinery until you know how the medicine affects you.

It may cause dizziness, drowsiness or tiredness in some people. Make sure you know how you react to the medicine before you drive a car, operate machinery, or do anything that could be dangerous.

Carers and other people who handle the tablets should wear disposable gloves to avoid direct contact with the tablets.

Pregnant women should not handle the medicine at all.

This medicine may cause harm to the unborn baby.

Because this medicine can reduce the ability of your immune system to fight infections, try to reduce the risk of infection. Maintain good hygiene. Some ways you can do this are:

- avoid people with infections if possible
- be careful when using a tooth brush, toothpick or dental floss
- be careful not to cut yourself
- avoid activities where you might be injured or bruised
- wear disposable gloves when cleaning, especially when cleaning up body fluid or waste
- dispose of gloves, rags or other items safely in a sealed plastic bag

Side effects

Be aware that taking more than the exact prescribed dose can be dangerous.

Suggested general statements to precede the lists of specific side effects:

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using this medicine.

This medicine may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor to answer any questions you may have.

The side effects listed for a particular product will depend on the PI and the company's disclosure policy.

Take care to include only those symptoms that the consumer can detect and do something about (refer to glossary of plain-English terms available from Medicines Australia or the ASMI website www.asmi.com.au).

The following possible side effect lists are placed in order of increasing urgency of the behaviour required. You may need to include one or more lists, depending on the PI.

If possible, take care not to duplicate side effects in more than one list so the consumer is not confused about the action that is required.

Add side effects in dot points, grouping like symptoms to keep the lists as short as possible.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- upset stomach, stomach pain, vomiting, nausea, loss of appetite
- dizziness
- hair loss
- mood changes or confusion
- ringing in the ears
- sore eyes

- increased sensitivity to sunlight
- unexplained weight loss
- tiredness or drowsiness
- weakness
- unusual or excessive thirst
- impotence or loss of interest in sex
- painful muscles and joints
- changes in menstrual cycle or unusual vaginal discharge
- *other common side effects, as per PI.*

The above list includes side effects that are usually mild or only last for a short time (*if consistent with the PI*).

Tell your doctor as soon as possible if you notice any of the following:

- headaches, shortness of breath when exercising, dizziness, looking pale – signs of anaemia
- bleeding or bruising more easily than usual
- seizures, fits or convulsions
- blurred vision, short term blindness
- difficulty speaking, writing or understanding language
- *other side effects, as per PI.*

The above list includes serious side effects that may require medical attention. Serious side effects are rare (*if consistent with frequencies in the PI*).

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- persistent diarrhoea
- mouth ulcers
- skin disorders, such as rash, ulceration or hives; itchy skin
- chest pain
- dry non-productive cough
- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- fever or chills – signs of infection

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- pain or difficulty urinating, lower back or side pain – signs of a possible kidney disorder
- yellowing of the skin or eyes, light coloured bowel motions, dark coloured urine, generally feeling unwell – signs of possible liver disease
- blood in urine or bowel motions, black tarry bowel motions, black vomit, pin-point red spots on the skin – signs of internal bleeding or other bleeding disorders
- *other side effects as per PI.*

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare (*if consistent with the frequencies in the PI*).

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Some of these side effects can only be found when your doctor does blood, urine or other tests from time to time to check your progress.

Tell your doctor immediately if you notice any of the side effects even after you have finished your treatment.

Some side effects of methotrexate may occur after you stop taking it.

After using [Medicine name]

This information will be product specific. Following are some examples from the Usability Guidelines. Choose whichever is appropriate or amend as necessary.

Storage

Do not store [Medicine name] or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

You may want to include a document code and/or a reference to the approved PI.

Product description

This information will be product specific. Following are some examples from the Usability Guidelines. Choose whichever is appropriate or amend as necessary.

What it looks like

Include colour, markings, any tablet scoring, colour and consistency of liquids, pack sizes, etc.

Ingredients

[Medicine name] contains x mg of methotrexate as the active ingredient. It also contains:

- *list excipients in dot points*

As appropriate, add This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Manufacturer/Distributor/Supplier

(use appropriate heading)

[Medicine name] is made/distributed/supplied in Australia by:

Include name and address of sponsor

® = Registered Trademark or
™ = Trademark (*if appropriate*)

This leaflet was prepared in *month/year*.

Include AUST R number(s)