

CHEXATE

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. Why am I taking CHEXATE?

CHEXATE tablets contain the active ingredient methotrexate (as sodium). CHEXATE is used to treat certain types of cancers, severe psoriasis (a skin condition) or severe rheumatoid arthritis when the condition does not improve with other medicines. For more information, see Section [1. Why am I taking CHEXATE?](#) in the full CMI.

2. What should I know before I take CHEXATE?

Do not use if you have ever had an allergic reaction to CHEXATE or any of the ingredients listed at the end of the CMI. Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant, or are breastfeeding.

For more information, see Section [2. What should I know before I take CHEXATE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CHEXATE and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take CHEXATE?

The dose of medicine given to you will depend on the condition being treated, your medical condition, your age, your size and how well your kidneys and liver are working.

More instructions can be found in Section [4. How do I take CHEXATE?](#) in the full CMI.

5. What should I know while taking CHEXATE?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking CHEXATE.• You and your partner must use a reliable method of contraception (e.g. birth control pills or condom) while taking CHEXATE and for at least six months after you stop treatment.• Discuss with your doctor how much water or fluids you should have since insufficient fluid intake can increase the side effects of this medicine.• Remind your doctor that you are taking CHEXATE if you are about to receive any vaccines.• Tell your doctor if you think you may be getting an infection (signs include fever, chills, achiness, sore throat).
Things you should not do	<ul style="list-style-type: none">• Do not go out in the sun without sunscreen and protective clothing. Do not use sun lamps.• Do not breastfeed while taking CHEXATE.
Driving or using machines	<ul style="list-style-type: none">• Do not drive or operate machinery until you know how CHEXATE affects you. CHEXATE may cause dizziness, drowsiness, blurred vision or tiredness affecting alertness.
Drinking alcohol	<ul style="list-style-type: none">• You must not drink alcohol while you are being treated with CHEXATE. Alcohol may increase the side effects of CHEXATE and cause liver damage.

For more information, see Section [5. What should I know while taking CHEXATE?](#) in the full CMI.

6. Are there any side effects?

Side effects include nausea, stomach pain, sore mouth (mouth ulcers, blisters), fatigue, generally feeling unwell, dizziness, drowsiness, blurred vision, sore eyes, ringing in ears and low numbers of blood cell counts. CHEXATE can cause serious side effects including severe allergic reaction; sore throat, fever, chills, achiness; severe skin rash with blistering; persistent cough, painful or difficulty breathing, or becoming breathless; spitting or coughing blood; skin rash and fever with swollen glands; swelling of the hands, ankles or feet; yellowing of the skin and eyes; loss of coordination, ability to speak or understand speech; weakness and inability to move one side of the body or the whole body, convulsions or fits.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

WARNING:

CHEXATE should only be taken for severe disease and when diagnosis has been made. It is a toxic medicine which can cause severe reactions and death. You should be treated under the constant care and follow up of your doctor or specialist.

Methotrexate should only be taken **ONCE A WEEK** to treat psoriasis and rheumatoid arthritis. Taking methotrexate more frequently than once a week may cause serious reactions and death. CHEXATE is available in two strengths. You should check to make sure that you are given the correct strength.

Methotrexate can cause blood disorders such as low numbers of red blood cells, white blood cells or platelets. At high or repeated doses, methotrexate may be toxic to your liver. Your doctor will need to do tests to check your liver regularly, before and during treatment. Avoid alcohol while being treated with methotrexate.

Tell your doctor if you have cancer of the lymphatic system as methotrexate can affect the treatment of this condition.

Serious infections, leading to death may occur with methotrexate treatment.

Methotrexate can cause birth defects, harm the unborn child or cause miscarriage. Methotrexate should not be taken by pregnant women or women who plan to become pregnant.

Methotrexate should not be started until it is confirmed you are not pregnant. If you become pregnant during treatment or think you might be pregnant, speak to your doctor as soon as possible. Your doctor will provide advice regarding the risk of harmful effects on the child through treatment.

You must avoid becoming pregnant or avoid fathering a child during treatment and for at least 6 months after the end of treatment.

Women should not breastfeed while taking methotrexate.

Methotrexate should not be taken if you have severe kidney problems.

Tell your doctor if you take medicines to relieve pain, swelling of inflammation (nonsteroidal anti-inflammatory drugs - NSAIDs) as this can result in serious side effects when taking methotrexate. It can affect your blood, stomach or gut and may lead to death.

Tell your doctor if you develop a dry, non-productive cough or shortness of breath. Your doctor will stop treatment and monitor you closely as these may be signs of damage to the lungs.

Use of methotrexate for non-cancer conditions in children has not been well established.

Tell your doctor if you are to have radiotherapy (also known as radiation therapy) while on methotrexate as this can cause damage to tissue and bone.

Tell your doctor if you are to have any vaccinations while on methotrexate as this may lead to serious infections or death.

CHEXATE

Active ingredient(s): *methotrexate (as sodium)*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking CHEXATE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking CHEXATE.**

Where to find information in this leaflet:

- [1. Why am I taking CHEXATE?](#)
- [2. What should I know before I take CHEXATE?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take CHEXATE?](#)
- [5. What should I know while taking CHEXATE?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking CHEXATE?

CHEXATE tablets contain the active ingredient methotrexate. Methotrexate belongs to a family of medicines called antineoplastics or cytotoxics. It may also be called a chemotherapy medicine.

CHEXATE is used to treat severe psoriasis (a skin condition) and severe rheumatoid arthritis. It is only used to treat these conditions if other treatments have not worked. It is also used to treat some types of cancers.

The medicine works by blocking an enzyme needed by the body's 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.

2. What should I know before I take CHEXATE?

Warnings

Do not take CHEXATE if:

- you are allergic to methotrexate, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you are pregnant
- you are breastfeeding
- you have severe kidney problems
- you have severe liver problems
- you are an alcoholic
- you have lowered immunity due to diseases or due to other treatments
- you have bone marrow disease.
- you have any blood disorders, or conditions which cause a low number of red blood cells, white blood cells, or platelets.
- you have low iron in the blood (anaemia)
- you have an infectious disease or severe infections
- you are receiving a live vaccine
- you are taking vitamin A derivatives (such as acitretin), medicines used to treat psoriasis and other skin conditions.

Do not take CHEXATE to treat psoriasis or rheumatoid arthritis if:

- you have stomach ulcers (peptic ulcer disease)
- have a condition where your large bowel is inflamed and have ulcers (ulcerative colitis).

Do not take CHEXATE if the expiry date printed on the pack is passed or if the packaging is torn or shows signs of tampering.

Check with your doctor if:

- you have any other medical conditions such as:
 - kidney problems
 - liver problems, including hepatitis B or hepatitis C
 - lung problems
 - diabetes
 - low folate levels
 - blood disorders including abnormal blood cell count
 - immune system disorder
 - infection or high temperature
 - stomach ulcer or ulcerative colitis (bleeding from your bowel)
 - lactose or galactose intolerance (CHEXATE contains lactose).

Before treatment is started your doctor may carry out blood tests to check the levels of cells in your blood, and also to check how well your kidneys and liver are working. You may also have a chest x-ray. Further tests may also be done during and after treatment.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and

how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

The medicine may harm the unborn child, cause birth defects and miscarriage if either you or your partner is taking it. Both you and your partner must use a reliable method of contraception (birth control pills or condom) during treatment with CHEXATE and for at least 6 months after you stop treatment. Your doctor will discuss with you what forms of contraception are suitable and when it is safe to stop using contraception if you wish to do so.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Methotrexate passes into the breast milk and should not be taken when breastfeeding.

Children and elderly

Special care will also be taken in children, the elderly and in those who are in poor physical condition.

3. What if I am taking other medicines?

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

Some medicines may interfere with CHEXATE and affect how it works.

These include:

- some antibiotics
- sulfonyleureas, medicines used to treat diabetes
- para-aminobenzoic acid, a medicine used to treat skin and autoimmune disorders
- diuretics, medicines to remove fluid or water from the body
- phenytoin, a medicine used to treat epilepsy
- ciclosporin and azathioprine, medicines used to prevent transplant organ rejection and other conditions
- vitamin supplements that contain folic acid or folinic acid (take your folic acid preparation on another day of the week, separate from CHEXATE)
- non-steroidal anti-inflammatory drugs (NSAIDs) and salicylates (e.g. aspirin), medicines used to relieve pain, swelling and inflammation
- disease modifying antirheumatic drugs (DMARDs), medicines used to slow down progression of rheumatoid arthritis
- allopurinol or probenecid, medicines used to treat gout
- theophylline, a medicine used to relieve asthma
- cholestyramine, a medicine used to lower high cholesterol
- amiodarone, a medicine used to treat heart disorders
- certain other medicines used to treat cancer
- sulfasalazine, a medicine used to treat Crohn's disease, ulcerative colitis and rheumatoid arthritis

- other medicines that may cause damage to your liver
- retinoids such as acitretin, medicines used to treat skin conditions
- pyrimethamine, a medicine used for malaria
- proton pump inhibitors, medicines used to treat stomach ulcers and reflux
- methoxsalen, a medicine used with ultraviolet light in PUVA therapy for skin conditions such as severe psoriasis

CHEXATE can also be affected by, or interfere with the following:

- nitrous oxide anaesthetics
- vaccines
- blood transfusions
- alcohol
- radiotherapy (radiation therapy), e.g. x-rays, ultraviolet radiotherapy

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect CHEXATE.

4. How do I take CHEXATE?

How much to take

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 CHEXATE to treat your condition.

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

When to take

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 to take it and for how long

Do not crush or chew the tablets. Swallow the tablets whole with a full glass of water.

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 CHEXATE

If you miss your dose at the usual time, contact your doctor or pharmacist for advice.

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

If you have any trouble remembering when to take your tablets, ask your pharmacist for help.

If you take too much CHEXATE

You will need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling **13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking CHEXATE?

Things you should do

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking CHEXATE.
- Tell any other doctors, dentists, and pharmacists who are treating you that you are taking this medicine
- If you are going to have surgery, tell the surgeon, anaesthetist or dentist that you are taking this medicine. It may affect other medicines used during surgery.
- If you are about to be given an immunisation, remind your doctor that you are taking this medicine.
- Check your tablets very carefully each time you collect them from your pharmacist.
CHEXATE is available in two strengths. You should check to make sure that you are given the correct strength.
- 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.
- Ask your doctor if there are any precautions you need to take to prevent your urine becoming too acidic. Acidic urine can increase the side effects of this medicine.
- Tell your doctor immediately if you are spitting or coughing up blood when taking CHEXATE. Some

patients have reported acute bleeding in the lungs when using methotrexate to treat rheumatoid arthritis and other related diseases.

- Keep all of your doctor's appointments so that your progress can be checked. Methotrexate can cause problems with your blood, liver and kidneys. Your doctor may organise blood and urine tests to check for these problems or may ask you to have an operation to have small sample of your liver tested. There may also be a chest x-ray and a physical examination to check for swelling of your lymph nodes (glands in your neck, armpits and groin).
- Keep using contraception. If you become pregnant, tell your doctor immediately.

Things you should not do

- Do not go out in the sun without wearing protective clothing (hat and shirt) and using a sunscreen with a high sun protection factor (SPF, e.g. 50+).
- Avoid exposure to sun lamps.

Methotrexate can increase your sensitivity to sunlight and cause severe reactions, increasing the risk of skin cancer (nonmelanoma and melanoma). Symptoms may include a skin rash, itching, swelling, redness, blistering or a severe sunburn.

Things to be careful of

Methotrexate can lower the number of white blood cells and platelets in your blood. This means that you have an increased chance of getting an infection or bleeding. The following precautions should be taken to reduce your risk of infection or bleeding:

- avoid people with infections. Check with your doctor immediately if you think you may be getting an infection, or if you get a fever, chills, cough, hoarse throat, lower back or side pain, or find it difficult to urinate.
- be careful when using a toothbrush, toothpick or dental floss. Your doctor, dentist, nurse or pharmacist may recommend other ways to clean your teeth and gums.
- be careful not to cut yourself when you are using sharp objects such as a razor or nail cutters.
- avoid contact sports or activities where you might be injured or bruised.

Methotrexate may be excreted in body fluids and waste, including blood, urine, faeces, vomit and semen. In general, precautions to protect other people should be taken while you are taking CHEXATE and for one week after the treatment period by:

- flushing the toilet twice to dispose of any body fluids and waste.
- wearing disposable gloves to clean any spill of body fluid or waste. Use paper towels or old rags, a strong solution of non-bleaching detergent and large amounts of water to mop up the spill. Discard the gloves, towels or rags into a separate waste bag and dispose of fluids in the toilet.
- washing linen or clothing that is heavily contaminated by body fluids or waste separately from other items.

Use a strong solution of non-bleaching detergent and large amounts of water.

- placing soiled disposable nappies and other pads in a plastic bag, seal and dispose into the garbage.
- for sexual intercourse, use a barrier method such as a condom.

Carers and other people who handle CHEXATE should wear disposable gloves to avoid direct contact with the tablets. Pregnant women should not handle the medicine at all.

Driving or using machines

Be careful before you drive, use any machines or tools, or do anything else that could be dangerous until you know how CHEXATE affects you.

CHEXATE may cause dizziness, drowsiness, blurred vision or tiredness in some people and therefore may affect alertness.

Drinking alcohol

You must not drink alcohol while you are being treated with this medicine.

Alcohol may increase the side effects of CHEXATE and cause liver damage.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Store below 25°C in a cool dry place away from moisture, heat or sunlight.

Do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

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

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects

Less serious side effects	What to do
Stomach or gut related: <ul style="list-style-type: none"> • vomiting, nausea, diarrhoea • upset stomach, stomach pain • lack of appetite, weight loss Nervous system related: <ul style="list-style-type: none"> • headaches, dizziness, drowsiness • weakness, numbness, tingling, burning or cold sensations • irritability, depression, confusion or mood changes Skin and nails related: <ul style="list-style-type: none"> • skin rash, itchiness • sensitivity or increased burning of the skin from sun exposure • acne, boils or skin ulcers • hair loss or infection of hair roots, especially of the scalp • changes in the toenails/fingernails or skin around the nails Eye and ear related: <ul style="list-style-type: none"> • conjunctivitis (itchy eyes and crusty eyelids) • sore eyes, blurred vision • ringing in the ears Blood related: <ul style="list-style-type: none"> • tiredness, headaches, shortness of breath, dizziness, looking pale (signs of anaemia) Others: <ul style="list-style-type: none"> • unusual or excessive thirst. • changes in menstrual cycle (period), unusual vaginal discharge • enlarged breast • impotence or loss of interest in sex • back pain, stiff neck • painful muscles or joints • muscle cramps or spasms • brittle bones 	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>

Serious side effects	What to do
Allergic reaction related: <ul style="list-style-type: none"> • signs of an allergic reaction 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 Eye related: <ul style="list-style-type: none"> • temporary blindness Lung related: <ul style="list-style-type: none"> • persistent dry, non-productive cough • shortness of breath, wheezing, difficulty breathing or chest pain • spitting or coughing blood 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
Heart and blood related: <ul style="list-style-type: none"> • fast or irregular heart beats, shortness of breath, chest pain, weakness or fatigue • pain, swelling, redness and warmth in the leg (signs of a blood clot in the leg) • weakness or paralysis on one side of the body or face, difficulty speaking or swallowing, headache, loss of balance or vision (signs of a stroke) Nervous system related: <ul style="list-style-type: none"> • seizures, fits or convulsions • difficulty speaking, writing or understanding language • weakness in the legs that spreads to the upper limbs and face, which may result in paralysis Infection related: <ul style="list-style-type: none"> • fever and chills, sore throat, sweating, body aches or feeling generally unwell • sore mouth (mouth ulcers, blisters), difficulty swallowing, cold sores, swollen glands Severe skin reaction related: <ul style="list-style-type: none"> • skin redness/rash, pinpoint red spots, ulceration, blistering; hives or itchy skin • severe blisters and bleeding in the lips, eyes, mouth, nose and genitals (Stevens-Johnson syndrome) Bleeding related: <ul style="list-style-type: none"> • blood in urine, vomit or bowel motion (e.g. black tarry stools, black vomit) • bleeding or bruising more easily than usual (e.g. bleeding gums, broken blood vessels) Kidney related: <ul style="list-style-type: none"> • swelling of hands, ankles or feet • frequent or painful urination, difficulty urinating, blood in urine, lower back or side pain Liver related: <ul style="list-style-type: none"> • yellowing of the skin and eyes, nausea, vomiting, loss of appetite, feeling generally unwell, fever, itchy or lighter patches on the skin, pale coloured stools, dark coloured urine 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

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 or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What CHEXATE tablets contain

Active ingredient (main ingredient)	methotrexate (as sodium)
Other ingredients (inactive ingredients)	lactose monohydrate microcrystalline cellulose magnesium stearate
Potential allergens	lactose

Do not take this medicine if you are allergic to any of these ingredients.

If you have galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption, check with your doctor before taking this medicine. CHEXATE contains lactose.

What CHEXATE looks like

CHEXATE 2.5 mg tablets are yellow, round, uncoated, flat tablet, with a cosmetic score line and engraved with ORN 57 on one side, diameter 6 mm (AUST R 380991).

The score line on the 2.5 mg tablet is only cosmetic and must not be used to divide the tablet into equal doses.

It comes in boxes of 24 or 30 and 100 tablets.

CHEXATE 10 mg tablets are yellow, capsule-shaped, convex, uncoated tablet, engraved with ORN 59 on one side and score on other side, length of 14 mm and width of 6 mm (AUST R 380990).

The 10 mg tablet can be divided into equal doses.

It comes in boxes of 10, 15 or 50 tablets.

Not all pack sizes are marketed.

Who distributes CHEXATE

Orion Pharma (Aus) Pty Limited
Level 24, Tower 3, 300 Barangaroo Avenue
Sydney NSW 2000, Australia
Telephone: 1800 861 913

This leaflet was prepared in January 2024.