

ARX-Methotrexate

Consumer Medicine Information (CMI) summary

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

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

1. Why am I taking ARX-Methotrexate?

ARX-Methotrexate contains the active ingredient methotrexate. ARX-Methotrexate is used to treat certain types of cancers, severe psoriasis or rheumatoid arthritis when the condition does not improve with other medicines.

For more information, see Section [1. Why am I taking ARX-Methotrexate?](#) in the full CMI.

2. What should I know before I take ARX-Methotrexate?

Do not take if you have ever had an allergic reaction to ARX-Methotrexate 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 ARX-Methotrexate?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ARX-Methotrexate 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 ARX-Methotrexate?

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 ARX-Methotrexate?](#) in the full CMI.

5. What should I know while taking ARX-METHOTREXATE?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking ARX-Methotrexate.• You and your partner must use a reliable method of contraception (birth control pills or condom) while taking ARX-Methotrexate and for at least three months after you stop treatment for men and six months after you stop treatment for women.• Discuss with your doctor how much water or fluids you should have as not enough fluid intake can increase the side effects of this medicine.• Remind your doctor you are on ARX-Methotrexate if you are about to receive any vaccination.• Tell your doctor if you think you may be getting an infection (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 ARX-Methotrexate.
Driving or using machines	<ul style="list-style-type: none">• Do not drive or operate machinery until you know how ARX-Methotrexate affects you. ARX-Methotrexate may cause dizziness, drowsiness, blurred vision or tiredness, affecting alertness.
Drinking alcohol	<ul style="list-style-type: none">• You must not drink alcohol whilst you are taking this medicine. Alcohol may increase the side effects of ARX-Methotrexate and cause liver damage.

For more information, see Section [5. What should I know while taking ARX-Methotrexate?](#) 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. ARX-Methotrexate can cause serious side effects including severe allergic reaction; sore throat, fever, chills, achiness; severe skin rash with blistering; persistent cough, pain 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:

ARX-Methotrexate 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. ARX-Methotrexate 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 be 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 three months after the end of treatment for men and six months after the end of treatment for women. Both you and your partner must use a reliable method of contraception (birth control pills or condom) during this period.

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.

ARX-Methotrexate

Active ingredient(s): *methotrexate*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking ARX-Methotrexate. **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 ARX-Methotrexate.**

Where to find information in this leaflet:

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

1. Why am I taking ARX-Methotrexate?

ARX-Methotrexate contains the active ingredient methotrexate.

ARX-Methotrexate is an antineoplastic or cytotoxic medicine. It may also be called a chemotherapy medicine.

ARX-Methotrexate is used to treat certain types of cancers. It may also be used in severe psoriasis or rheumatoid arthritis when the condition does not improve with other medicines.

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 ARX-Methotrexate?

Warnings

Do not take ARX-Methotrexate 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 take this medicine.
- you are pregnant.
- you are breastfeeding.
- you have severe kidney problems.
- you have severe liver problems.
- are an alcoholic.
- you have lowered immunity due to diseases or due to other treatments.
- have bone marrow disease.

- have any blood disorders, or conditions which cause a low number of red blood cells, white blood cells, or platelets.
- have low iron in the blood (anaemia).
- have 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 ARX-Methotrexate to treat psoriasis and rheumatoid arthritis if you:

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

Check with your doctor if you:

- have any other medical conditions
 - 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 (ARX-Methotrexate 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 ARX-Methotrexate and for at least

three months after you stop treatment for men and at least six months after stopping treatment for women. 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 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 ARX-Methotrexate and affect how it works.

These include:

- some antibiotics
- sulphonylureas, 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.
- vitamin supplements that contain folic acid or folinic acid (take your folic acid preparation on another day of the week, separate from ARX-Methotrexate).
- non-steroidal anti-inflammatory medicines (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 disease.
- allopurinol and 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, medicines used to treat skin conditions such as acitretin.
- 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 conditions such as severe psoriasis.

ARX-Methotrexate can also be affected by, or interfere with the following:

- nitrous oxide anaesthetics
- vaccines
- blood transfusions
- alcohol
- radiotherapy (radiation therapy) e.g. x-rays, ultra violet 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 ARX-Methotrexate.

4. How do I take ARX-Methotrexate?

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 ARX-Methotrexate to treat your condition.

There are different doses for rheumatoid arthritis or psoriasis, and cancer. It is important not to take ARX-Methotrexate 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

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 ARX-Methotrexate

If you forget to take a dose, 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 ARX-Methotrexate

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 ARX-Methotrexate?

Things you should do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking ARX-Methotrexate.

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.

ARX-Methotrexate 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 ARX-Methotrexate.

Some patients have reported acute bleeding in the lungs when taking ARX-Methotrexate to treat rheumatoid arthritis and other related diseases.

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

Methotrexate can cause problems with your blood, liver and kidneys. Your doctor may do blood tests to check for these problems or may ask you to have an operation to have a small sample of your liver removed. 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).

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 protection factor. Avoid exposure to sunlamps.

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

Things to be careful of

ARX-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 who have 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 painful or 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. Check with your doctor before having any dental work.
- Be careful not to cut yourself when you are using sharp objects such as a razor or nail cutters.
- Avoid contact sports or other situations where you may bruise or get injured.

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 ARX-Methotrexate and for one week after the treatment period by:

- Flushing the toilet twice to dispose of any body fluids and waste.
- Wearing gloves to clean any spill of body fluid or waste. Use paper towels or old rags, a strong solution of nonbleaching detergent and large amounts of water to mop up the spill. Discard the 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 ARX-Methotrexate 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 ARX-Methotrexate affects you.

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

Drinking alcohol

You must not drink alcohol whilst you are being given this medicine.

Alcohol may increase the side effects of ARX-Methotrexate and cause liver damage.

Looking after your medicine

Do not store ARX-Methotrexate 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.

It should be kept in a cool dry place, protected from light, where the temperature stays below 25°C.

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

Side effects	What to do
Stomach or gut related <ul style="list-style-type: none"> • nausea, vomiting, diarrhoea • upset stomach or stomach pains 	Speak to your doctor if you have any of these side effects and they worry you.

<ul style="list-style-type: none"> • lack of appetite or weight loss 	
Nervous system related <ul style="list-style-type: none"> • dizziness, drowsiness, headaches • numbness, weakness, 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 or boils or skin ulcers • infection of hair roots or hair loss, 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) 	
Other <ul style="list-style-type: none"> • unusual or excessive thirst • changes in menstrual cycle (periods), unusual vaginal discharge • enlarged breast • impotence or loss of interest in sex • back pain, stiff neck • painful joints or muscles • muscle cramps or spasms • brittle bones 	

Serious side effects

Serious side effects	What to do
Allergic reaction related <ul style="list-style-type: none"> • signs of an allergic reaction, such as shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the 	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>body; rash, itching, or hives on the skin.</p> <p>Heart and blood related</p> <ul style="list-style-type: none"> • chest pain, shortness of breath, fast or irregular heart beats, 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 stroke) • rapid weight gain, fluid retention, swollen ankles <p>Eye related</p> <ul style="list-style-type: none"> • temporary blindness <p>Lung related</p> <ul style="list-style-type: none"> • persistent dry, non-productive cough • wheezing, difficulty breathing or chest pain • Shortness of breath which may be worse when lying down, cough spitting or coughing up blood or pinkish mucus (may be due to build up of fluid in the lungs called pulmonary oedema) • <p>Nervous system related</p> <ul style="list-style-type: none"> • fits, seizures or convulsions • difficulty speaking, writing or understanding language • weakness in the legs that spreads to the upper limbs and the face, which may result in paralysis <p>Infection related</p> <ul style="list-style-type: none"> • fever and chills, sore throat, sweats, body 		<p>aches or feel generally unwell</p> <ul style="list-style-type: none"> • sore mouth (mouth ulcers, blisters), difficulty swallowing, cold sores, swollen glands • headache, dizziness, vomiting, loss of coordination or confusion (may be due to build up of fluid in the brain called brain oedema). <p>Severe skin reaction related</p> <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) <p>Bleeding related</p> <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) <p>Kidney related</p> <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 <p>Liver related</p> <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 	
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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.

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

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.

Cipla Australia Pty Ltd.,
Level 1 / 132-136 Albert road,
South Melbourne Vic 3205.
drugsafety@cipla.com
Phone: 1800-569-074

This leaflet was prepared in March 2024.

7. Product details

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

What ARX-Methotrexate contains

Active ingredient (main ingredient)	methotrexate
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• lactose monohydrate• sodium starch glycollate type A• purified talc• calcium hydrogen phosphate• microcrystalline cellulose• magnesium stearate
Potential allergens	<ul style="list-style-type: none">• lactose monohydrate

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

What ARX-Methotrexate looks like

ARX-Methotrexate 2.5 mg tablets are yellow, circular, biconvex, uncoated tablets plain on both sides. Available in packs of 30 tablets.

ARX-Methotrexate 10 mg tablets are yellow, capsule shaped, biconvex, uncoated tablet with central break line on one side and plain on other side. Available in packs of 10, 15, 30 and 50 tablets.

Australian Registration Number

- 2.5 mg: AUST R 365580
- 10 mg: AUST R 365590

Who distributes ARX-Methotrexate