

METHOTREXATE ACCORD

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.

1. Why am I being given Methotrexate Accord?

Methotrexate Accord contains the active ingredient methotrexate. Methotrexate Accord belongs to a group of medicines known as antineoplastic or cytotoxic agents.

Methotrexate Accord is used to treat some types of cancers. It may also be used in severe psoriasis when these conditions do not improve with other medicines.

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

2. What should I know before I am given Methotrexate Accord?

Do not use if you have ever had an allergic reaction to 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 am given Methotrexate Accord?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines and methotrexate may interfere with each other and may affect how well each medicine works.

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

4. How will I be given Methotrexate Accord?

Methotrexate Accord will be given to you by a doctor or a nurse as an injection into a muscle, a vein, an artery or into the spine.

More instructions can be found in Section [4. How will I be given Methotrexate Accord?](#) in the full CMI.

5. What should I know while being given Methotrexate Accord?

Things you should do	<ul style="list-style-type: none">• Be sure to keep all your doctor's appointments• Use an effective method of birth control while you are being treated with methotrexate or for at least 6 months after stopping treatment• If you or your partner becomes pregnant while you are being treated with methotrexate, or for up to 6 months afterwards, tell your doctor immediately• Tell your doctor if you have an infection or high temperature• Protect your skin when you are in the sun. Avoid exposure to sunlamps• Discuss with your doctor how much water or fluids you should have whilst you are being given it• Remind your doctor if you are about to receive any vaccination
Things you should not do	<ul style="list-style-type: none">• Do not breast-feed if you are being treated with Methotrexate Accord• Do not drink alcohol whilst you are being given this medicine
Driving or using machines	Be careful driving or operating machinery until you know how Methotrexate Accord affects you. Methotrexate Accord may cause dizziness, drowsiness or tiredness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

For more information, see Section [5. What should I know while being given Methotrexate Accord?](#) in the full CMI.

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.

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. Pfizer Methotrexate Injection can cause serious side effects including severe allergic reaction; sore throat, fever, chills, achiness; severe skin rash with blistering; injection site reactions, 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.

METHOTREXATE ACCORD

Active ingredient(s): *Methotrexate*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I being given Methotrexate Accord?

Methotrexate Accord contains the active ingredient methotrexate. Methotrexate Accord belongs to a group of medicines called antineoplastic or cytotoxic medicines. You may also hear of these being called chemotherapy medicines. This medicine works by blocking an enzyme needed by body cells to live. This interferes with the growth of some cells that are growing rapidly, such as skin cells in psoriasis and cancer cells.

Methotrexate Accord is used to treat some types of cancers. It may also be used in severe psoriasis when these conditions do not improve with other medicines.

Your doctor, however, may prescribe Methotrexate Accord for another purpose.

2. What should I know before I am given Methotrexate Accord?

Warnings

You must not be given Methotrexate Accord if:

- you have an allergy to methotrexate or any of the ingredients listed at the end of this leaflet
- you have/have had severe kidney problems
- you have/have had lowered immunity due to diseases such as HIV/AIDS, or lowered immunity due to other treatments
- you are going to be vaccinated with a live vaccine

You must not be given this medicine to treat psoriasis if you have or have had any of the following:

- any blood disorders, or conditions which cause a reduced number of red blood cells, white blood cells, or platelets
- bone marrow disease

- anaemia (low iron in the blood)
- liver problems
- stomach ulcers (peptic ulcer disease)
- ulcerative colitis, a condition where your colon (large bowel) is inflamed and has ulcers
- alcoholism

Tell your doctor if you have or have had:

- allergies to any other medicines, foods, preservatives or dyes
- kidney problems
- lung problems
- diabetes
- folate deficiency

If you are taking this medicine to treat cancer, tell your doctor if you have or have had:

- any blood disorders, or conditions that cause a reduced number of red blood cells, white blood cells, or platelets
- bone marrow disease
- anaemia (low iron in the blood)
- stomach ulcers (peptic ulcer disease)
- liver problems
- ulcerative colitis, a condition where your colon (large bowel) is inflamed and has ulcers

Pregnancy and breastfeeding

Do not use Methotrexate Accord if you are pregnant. Like most cytotoxic medicines methotrexate is not recommended for use during pregnancy. If there is any need to consider methotrexate during your pregnancy, your doctor or pharmacist will discuss with you the benefits and risks of using it.

Methotrexate may cause birth defects if either the male or female is using it at the time of conception. It is recommended that you use a barrier method of birth control while you are using methotrexate and for at least 6 months after you stop treatment. Your doctor will discuss this with you.

Tell your doctor or pharmacist if you or your partner are pregnant or intend to become pregnant.

Do not breast-feed if you are being treated with this medicine. Methotrexate passes into breast milk and there is a possibility that your baby may be affected.

General

You must not be given this medicine if you are taking acitretin (a medicine to treat psoriasis and other skin disorders).

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.

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?](#)

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 and methotrexate may interfere with each other. These include:

- some antibiotics, including tetracyclines, penicillins, sulphonamides, trimethoprim, chloramphenicol, pristinamycin and ciprofloxacin
- sulphonylureas, a group of medicines used to treat diabetes
- para-aminobenzoic acid, a medicine used to treat skin and autoimmune disorders
- phenytoin, a medicine used to treat epilepsy
- ciclosporin and azathioprine, medicines used to prevent transplant organ rejection
- corticosteroids such as hydrocortisone and prednisolone
- folic acid or folinic acid (which may be present in multi-vitamin preparations)
- non-steroidal anti-inflammatory medicines (NSAIDs) and salicylates, medicines used to relieve pain, swelling and other symptoms of inflammation (such as aspirin, diclofenac, indomethacin, ketoprofen, naproxen, phenylbutazone)
- disease modifying antirheumatic drugs (DMARDs), medicines used to slow down progression of rheumatoid arthritis disease
- allopurinol and probenecid, medicines used to treat gout
- medicines for psoriasis such as etretinate
- theophylline, a medicine used to relieve asthma
- fluid tablets
- cholestyramine, a medicine used to lower high cholesterol
- amiodarone, a medicine used to treat heart disorders
- other medicines used to treat cancer (such as cisplatin, asparaginase, mercaptopurine)
- 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, such as omeprazole, pantoprazole
- methoxsalen (a medicine used with ultraviolet light in PUVA therapy for conditions such as severe psoriasis)

Methotrexate Accord can also be affected by the following:

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

These medicines may be affected by methotrexate, or may affect how well it works. You may need different amounts

of your medicines, or you may need to take different medicines. Your doctor or pharmacist will advise you.

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

4. How will I be given Methotrexate Accord?

How much will be given

Your doctor will decide what dose of methotrexate you will receive. This depends on your condition and other factors, such as your weight, and other medicines you are being given.

This medicine may be given alone or in combination with other drugs. It may be given as a short course or on an ongoing basis.

Additional treatment may not be repeated until your blood cell numbers return to acceptable levels and any unwanted effects have been controlled.

For cancer treatment, several courses of methotrexate therapy may be needed depending on your response to treatment.

For the treatment of psoriasis, methotrexate therapy is usually required long term.

How it is given

Methotrexate Accord may be given as an injection into a muscle, a vein, an artery or into the spine.

If you receive too much Methotrexate Accord

Since Methotrexate Accord is usually given to you in hospital under the supervision of your doctor or nurse, it is very unlikely that you will be given too much of the medicine. If you think that you have been given too much Methotrexate Accord.

You should immediately:

- contact your doctor or nurse
- phone the Poisons Information Centre (**by calling 13 11 26**)

5. What should I know while being given Methotrexate Accord?

Things you must do

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

Your doctor may want to check your blood pressure and do some blood and other tests from time to time to check on your progress and to check for any unwanted side effects.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being given Methotrexate Accord.

Tell any other doctors, dentists, and pharmacists who treat you that you are being given Methotrexate Accord.

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

A barrier method of birth control, such as a condom, should be used while you are being treated with methotrexate and for at least 6 months after stopping treatment. Your doctor will tell you what forms of contraception are suitable and when it is safe to stop using contraception if you wish to do so.

If you or your partner becomes pregnant while you are being treated with methotrexate, or for up to 6 months afterwards, tell your doctor immediately.

Protect your skin when you are in the sun, especially between 10am and 3pm. If outdoors, wear protective clothing and use a 15+ (minimum) sunscreen. Avoid exposure to sunlamps. Methotrexate may cause your skin to be much more sensitive to sunlight than it is normally and there is an increased risk of skin cancer (melanoma and non-melanoma). Exposure to sunlight may cause a skin rash, itching, redness, or a severe sunburn.

Discuss with your doctor how much water or fluids you should have whilst you are being given this medicine. Inadequate fluid intake can increase the side effects of this medicine.

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.

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, vomitus and semen. In general, precautions to protect other people should be taken while you are receiving 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 non-bleaching 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

Things you must not do

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

Alcohol may increase the side effects of methotrexate.

Driving or using machines

Be careful driving or operating machinery or doing jobs that require you to be alert until you know how Methotrexate Accord affects you.

Methotrexate Accord may cause dizziness, drowsiness or tiredness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Looking after your medicine

The hospital will store Methotrexate Accord under the correct conditions.

Getting rid of any unwanted medicine

Your doctor or pharmacist will dispose of any Methotrexate Accord that may be left over.

Do not use 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.

If you are over 65 years of age you may have an increased chance of getting side effects.

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
<p>Stomach or gut related</p> <ul style="list-style-type: none"> • nausea, vomiting, diarrhoea • upset stomach or stomach pains • lack of appetite or weight loss <p>Nervous system related</p> <ul style="list-style-type: none"> • dizziness, drowsiness, headaches • numbness, weakness, tingling, burning or cold sensations • irritability, depression, confusion or mood changes <p>Skin and nails related</p> <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 	<p>Speak to your doctor if you have any of these side effects and they worry you</p>

<p>Eye and ear related</p> <ul style="list-style-type: none"> • conjunctivitis (itchy eyes and crusty eyelids) • sore eyes, blurred vision • ringing in the ears <p>Blood related</p> <ul style="list-style-type: none"> • tiredness, headaches, shortness of breath, dizziness, looking pale (signs of anaemia) <p>Other</p> <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 • injection site reactions 	
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The above list includes side effects which are usually mild or short-lived.

Serious side effects

Serious side effects	What to do
<p>Allergic reaction related</p> <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 body; rash, itching, or hives on the skin <p>Heart and blood related</p> <ul style="list-style-type: none"> • chest pain, shortness of breath, fast or irregular heartbeats, 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, 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 buildup of fluid in the lungs called pulmonary oedema). 	<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
<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 • headache, dizziness, vomiting, loss of coordination or confusion (may be due to buildup of fluid in the brain called brain oedema). <p>Infection related</p> <ul style="list-style-type: none"> • fever and chills, sore throat, sweats, body aches or feel generally unwell • sore mouth (mouth ulcers, blisters), difficulty swallowing, cold sores, swollen glands <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) • dark red or black patches of skin around the injection site <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 	

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

Other side effects not listed above 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.

The benefits and side effects of methotrexate may take some time to occur. Therefore, even after you have finished your methotrexate treatment you should tell your doctor immediately if you notice any of the side effects listed in this section.

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.

Methotrexate Accord does not contain gluten, sucrose, lactose, tartrazine or any other azo dyes.

It is not addictive.

What Methotrexate Accord contains

Active ingredient (main ingredient)	methotrexate
Other ingredients (inactive ingredients)	sodium hydroxide water for injections sodium chloride (only in the 50 mg/2 mL strength)

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

What Methotrexate Accord looks like

Methotrexate Accord is a clear yellow to orange solution in glass vials.

(50 mg/2 mL: AUST R 213736, 1000 mg/10 mL: AUST R 213737)

Who distributes Methotrexate Accord

Accord Healthcare Pty Ltd
Level 24, 570 Bourke Street
Melbourne, VIC, 3000
Australia

This leaflet was prepared in January 2024.