

DBL™ Methotrexate Injection

Consumer Medicine Information (CMI) summary

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#) on the next page. Read the full CMI before using this medicine. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being treated with DBL Methotrexate Injection?

DBL Methotrexate Injection contains the active ingredient methotrexate. DBL Methotrexate Injection 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 being treated with DBL Methotrexate Injection?](#) in the full CMI.

2. What should I know before treatment with DBL Methotrexate Injection?

Do not use if you have ever had an allergic reaction to DBL Methotrexate Injection 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 treatment with DBL Methotrexate Injection?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DBL Methotrexate Injection 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 is DBL Methotrexate Injection given?

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 is DBL Methotrexate Injection given?](#) in the full CMI.

5. What should I know during treatment with DBL Methotrexate Injection?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using DBL Methotrexate.You and your partner must use a reliable method of contraception (birth control pills or condom) during treatment with DBL Methotrexate, and for at least 6 months for females, and 3 months for males, after stopping treatment.Discuss with your doctor how much water or fluids you should have as insufficient fluid intake can increase the side effects of this medicine.Remind your doctor you are on DBL 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 using DBL Methotrexate.
Driving or using machines	<ul style="list-style-type: none">Do not drive or operate machinery until you know how DBL Methotrexate affects you. DBL 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 being given this medicine. Alcohol may increase the side effects of DBL Methotrexate and cause liver damage.
Looking after your medicine	<ul style="list-style-type: none">DBL methotrexate is stored in the pharmacy or kept on the hospital ward at temperature below 25°C.

For more information, see Section [5. What should I know during treatment with DBL Methotrexate Injection?](#) in the full CMI.

6. Are there any side effects?

Side effects may 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, as well as severe allergic reaction; sore throat, fever, injection site reactions, persistent cough, pain or difficulty breathing. 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:

Methotrexate should only be used once a week to treat certain conditions. Using methotrexate more frequently than once a week for these conditions may cause serious reactions and death.

Methotrexate may cause significant toxicities which can cause severe reactions and death. One of which is disorders of the blood 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 and/or kidney.

Serious infections, leading to death, may occur with methotrexate treatment. Methotrexate may have severe impact on your stomach or gut, on your skin, blood, immunity, and may lead to death.

Methotrexate should not be used in pregnant women or women who plan to become pregnant. Methotrexate can cause birth defects, harm to an unborn child or cause miscarriage. Women should not breastfeed while being treated with methotrexate.

DBL™ Methotrexate Injection

Active ingredient(s): *methotrexate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using DBL Methotrexate Injection. **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 DBL Methotrexate Injection.**

Where to find information in this leaflet:

- [1. Why am I being treated with DBL Methotrexate Injection?](#)
- [2. What should I know before treatment with DBL Methotrexate Injection?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is DBL Methotrexate Injection given?](#)
- [5. What should I know during treatment with DBL Methotrexate Injection?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being treated with DBL Methotrexate Injection?

DBL Methotrexate Injection contains the active ingredient methotrexate.

DBL Methotrexate Injection 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.

DBL Methotrexate Injection is known as an antineoplastic or cytotoxic medicine. It may also be called a chemotherapy medicine. 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 treatment with DBL Methotrexate Injection?

Warnings

Do not use DBL Methotrexate Injection 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, plan to be pregnant,
- You are breastfeeding,
- You have severe kidney or liver problems,
- You suffer from alcoholism,
- You have poor nutrition,
- You suffer from illnesses impacting the bone marrow or the blood [including anaemia (low levels of iron in the blood), low red cell count, low white cell count or platelets],
- You have lowered immunity due to diseases or due to other treatments,
- You have certain disorders of the stomach (peptic ulcer disease) or gut (inflamed large bowel or ulcers),
- You are receiving a live vaccine,
- You are taking vitamin A derivatives (such as acitretin or other retinoids), medicines used to treat psoriasis and other skin conditions,
- You are receiving radiotherapy (radiation therapy) e.g. x-rays, ultra violet radiotherapy.

Use in children

Aside from its established use in some conditions, methotrexate use in children has not been fully researched. Methotrexate is not recommended in paediatric patients.

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).

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.

Pregnancy should be avoided if either partner is receiving methotrexate, during and after cessation of therapy. The medicine may harm the unborn child, cause birth defects and miscarriage if either you or your partner is using it. Both you and your partner must use a reliable method of contraception (birth control pills or condom) during treatment with DBL Methotrexate Injection and for at least 6 months for females and 3 months for males after stopping 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.

DBL Methotrexate Injection passes into breast milk and should not be used when breastfeeding.

Methotrexate can impair fertility in both men and women.

Men should seek advice from their doctor on preserving sperm before starting treatment. You should avoid fathering a child if you are being given methotrexate at the time and for at least 3 months after the end of your treatment.

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 DBL Methotrexate Injection 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,
- 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,
- 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,

DBL Methotrexate Injection 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 DBL Methotrexate Injection.

4. How is DBL Methotrexate Injection given?

How much and when is it given

Your doctor will decide what dose, how often and how long you will receive it. This depends on your condition and other factors, such as your weight, age, blood tests, how well your kidneys and liver are working, and whether or not other medicines are being given at the same time.

Methotrexate should only be used once a week to treat certain conditions. Using methotrexate more frequently than once a week for these conditions may cause serious reactions and death.

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.

How DBL Methotrexate Injection is given

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

DBL Methotrexate Injection must only be given by a doctor or nurse.

If you use too much DBL Methotrexate Injection

As DBL Methotrexate Injection is given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

Symptoms of a DBL Methotrexate Injection overdose may include the side effects listed in section 6, but are usually of a more severe nature. They may include blood in your bowel motions (black tarry stools), bleeding, nausea, vomiting, mouth ulcers and severe infections.

If you think that you have been given too much DBL Methotrexate Injection or experience any side effects, tell your doctor immediately.

5. What should I know during treatment with DBL Methotrexate Injection?

Things you should do

- Remind your doctor and pharmacist that you are being given DBL Methotrexate Injection:
 - If you are about to be started on any new medicine,
 - If you are about to be given an immunisation,
- Tell any other doctors, dentists, surgeons and pharmacists who are treating you that you are being given this medicine.
- 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.
- Tell your doctor immediately if you are spitting or coughing up blood when using DBL Methotrexate Injection.

Some patients have reported acute bleeding in the lungs when using DBL Methotrexate Injection 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 sun protection factor (SPF). Avoid exposure to sunlamps.

DBL Methotrexate Injection 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

DBL Methotrexate Injection 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.

DBL Methotrexate Injection 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 receiving DBL Methotrexate Injection 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.

Carers and other people who handle the injection should wear disposable gloves to avoid direct contact with the injection fluid. 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 DBL Methotrexate Injection affects you.

DBL Methotrexate Injection 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 DBL Methotrexate Injection and cause liver damage.

Looking after your medicine

DBL Methotrexate Injection is usually stored in the pharmacy, doctor's surgery or on the ward. It is 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
<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>Eye and ear related</p> <ul style="list-style-type: none"> Conjunctivitis (itchy eyes and crusty eyelids) Sore eyes, blurred vision 	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>

<ul style="list-style-type: none"> 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 	
<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 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 	<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>

- 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 build up of fluid in the brain called brain oedema)

Infection related

- Fever and chills, sore throat, sweats, body aches or feel generally unwell
- Sore mouth (mouth ulcers, blisters), difficulty swallowing, cold sores, swollen glands

Severe skin reaction related

- 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

Bleeding related

- 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

- Swelling of hands, ankles or feet
- Frequent or painful urination, difficulty urinating, blood in urine, lower back or side pain

Liver related

- 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

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the New Zealand Pharmacovigilance Centre (NZPhvC) online at <https://pophealth.my.site.com/carmreportnz/s/>. 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 DBL Methotrexate Injection contains

Active ingredient (main ingredient)	Methotrexate
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • Water for injections • Sodium chloride • Hydrochloric acid (as pH-adjustment agent) • Sodium hydroxide (as pH-adjustment agent)

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

What DBL Methotrexate Injection looks like

DBL Methotrexate Injection is a clear yellow liquid in clear glass vials.

DBL Methotrexate Injection is available in the following strengths and pack sizes:

- 5 mg/2 mL vial x 5
- 50 mg/2 mL vial x 5
- 500 mg/20 mL vial x 1

Who distributes DBL Methotrexate Injection

Pfizer New Zealand Limited

PO Box 3998

Auckland

Toll Free Number: 0800 736 636

www.pfizermedicalinformation.co.nz

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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.