

DBL™ Methotrexate Injection

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

2. What should I know before I use 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 I use 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 do I use DBL Methotrexate Injection?

- 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 use DBL Methotrexate Injection?](#) in the full CMI.

5. What should I know while using 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 not enough 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.

For more information, see Section [5. What should I know while using DBL Methotrexate Injection?](#) 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. DBL 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.

WARNING:

DBL Methotrexate Injection should only be used 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 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 used in 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 3 months for men and 6 months for women after the end of treatment. 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 being treated with methotrexate.

Methotrexate should not be used 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 being treated with 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 psoriasis conditions in children has not been well established.

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.

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.

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 using DBL Methotrexate Injection?](#)
- [2. What should I know before I use DBL Methotrexate Injection?](#)
- [3. What if I am taking other medicines?](#)

- [4. How do I use DBL Methotrexate Injection?](#)
- [5. What should I know while using DBL Methotrexate Injection?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using DBL Methotrexate Injection?

DBL Methotrexate Injection contains the active ingredient methotrexate.

DBL Methotrexate Injection is an antineoplastic or cytotoxic medicine. It may also be called a chemotherapy medicine.

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.

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 use DBL Methotrexate Injection?

Warnings

Do not use DBL Methotrexate Injection if:

1. 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
2. you have severe kidney problems
3. you have lowered immunity due to diseases or due to other treatments
4. you are breastfeeding
5. you are taking vitamin A derivatives (such as acitretin), medicines used to treat psoriasis and other skin conditions
6. you are receiving radiotherapy (radiation therapy) e.g. x-rays, ultra violet radiotherapy
7. you are receiving a live vaccine

Do not use DBL Methotrexate Injection to treat psoriasis or rheumatoid arthritis if you:

1. are pregnant
2. have poor nutrition
3. have any blood disorders, or conditions which cause a low number of red blood cells, white blood cells, or platelets
4. have bone marrow disease
5. have low iron in the blood (anaemia)
6. have liver or severe kidney problems
7. are an alcoholic
8. have infectious disease or severe infections
9. have stomach ulcers (peptic ulcer disease)
10. 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)

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

Methotrexate can impair fertility in both men and women.

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 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.

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
- 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

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 do I use DBL Methotrexate Injection?

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 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 will most likely be given to you in hospital or under the supervision of your doctor, it is very unlikely that you will receive an overdose.

If you think that you have been given too much DBL Methotrexate Injection or experience severe side effects, you may need urgent medical attention.

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.

You should immediately:

- phone the National Poisons Centre (telephone 0800 POISON or 0800 764 766), 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 using DBL Methotrexate Injection?

Things you should do

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

Tell any other doctors, dentists, and pharmacists who are treating you that you are being given 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 using 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 protection factor. 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 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>Speak to your doctor if you have any of these side effects and they worry you.</p>

Side effects	What to do
<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>Speak to your doctor if you have any of these side effects and they worry you.</p>

Serious side effects	What to do
<p>Allergic reaction related</p>	<p>Call your doctor straight away,</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) spitting or coughing blood <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 build up 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 	<p>or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>
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<ul style="list-style-type: none"> 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 	
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What DBL Methotrexate Injection contains

Active ingredient (main ingredient)	methotrexate
Other ingredients (inactive ingredients)	water for injections sodium chloride sodium hydroxide 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.pfizermedinfo.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.

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://nzphvc.otago.ac.nz/reporting/>. 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.

Document Approval Record

Document Name:

CMI DBL Methotrexate Solution for Injection NZ

Document Title:

CMI DBL Methotrexate Solution for Injection NZ

Signed By:

Date(GMT)

Signing Capacity

Lu, Phuong

04-Oct-2023 01:51:57

Regulatory Affairs Approval