

DBL™ Methotrexate Injection

Methotrexate (Meth-o-TREX-ate)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL™ Methotrexate Injection. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given methotrexate against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What DBL™ Methotrexate Injection is used for

Methotrexate is used to treat some types of cancers. It may also be used in severe psoriasis when this condition does not improve with other medicines.

This medicine 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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

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

Before you are given DBL™ Methotrexate Injection

When you must not be given it

You must not be given DBL™ Methotrexate Injection if you have an allergy to:

- any medicine containing methotrexate
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching, or hives on the skin.

Females: tell your doctor or pharmacist if you are pregnant or intend to become pregnant.

Like most cytotoxic medicines DBL™ Methotrexate Injection is not recommended for use during pregnancy. If there is any need to consider DBL™ Methotrexate Injection during your pregnancy, your doctor or pharmacist will discuss with you the benefits and risks of using it.

Males: tell your doctor or pharmacist if your partner intends to become pregnant while you are being given DBL™ Methotrexate Injection or shortly after you have stopped treatment with DBL™ Methotrexate Injection.

DBL™ Methotrexate Injection may cause birth defects if either the male or female is using it at the time of conception. It is recommended that you use some kind of birth control while you are

using DBL™ Methotrexate Injection and for at least 12 weeks after you stop treatment. A barrier method of birth control, such as a condom, should be used while you are being given DBL™ Methotrexate Injection and for the first week of this 12-week period. Your doctor will discuss this with you.

Do not breast-feed if you are being treated with this medicine.

DBL™ Methotrexate Injection passes into breast milk and there is a possibility that your baby may be affected.

You must not be given this medicine if you have or have had any of the following medical conditions:

- severe kidney problems
- lowered immunity due to diseases such as HIV/AIDS, or lowered immunity due to other treatments.

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

- 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.

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.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- 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 of the following medical conditions:

- 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.

If you have not told your doctor about any of the above, tell him/her before you start being given DBL™ Methotrexate Injection.

Taking other medicines

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

Some medicines and DBL™ Methotrexate Injection may interfere with each other. These include:

- some antibiotics, including tetracyclines, penicillins, sulphonamides, trimethoprim and chloramphenicol
- sulphonylureas, a group of medicines used to treat diabetes
- phenytoin, a medicine used to treat epilepsy
- 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)
- 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
- other medicines used to treat cancer (such as cisplatin, asparaginase, mercaptopurine)
- medicines which can affect the liver such as azathioprine, leflunomide, retinoids or sulfasalazine
- pyrimethamine, a medicine used for malaria
- proton pump inhibitors, such as omeprazole, esomeprazole and pantoprazole
- methoxsalen (a medicine used with ultraviolet light in PUVA therapy for conditions such as severe psoriasis).

These medicines may be affected by DBL™ Methotrexate Injection, or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Tell your doctor if you are due to receive any vaccinations.

You should not receive certain vaccinations while being treated with DBL™ Methotrexate Injection.

Your doctor and pharmacist may have more information on medicines/vaccinations to be careful with or avoid while you are being treated with DBL™ Methotrexate Injection.

How DBL™ Methotrexate Injection is given

How much is given

Your doctor will decide what dose of DBL™ Methotrexate Injection 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 DBL™ Methotrexate Injection therapy may be needed depending on your response to treatment.

For the treatment of psoriasis, DBL™ Methotrexate Injection therapy is usually required long term.

Ask your doctor if you want to know more about the dose of DBL™ Methotrexate Injection you receive.

How it 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 have too much (overdose)

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. However, if you experience severe side effects tell your doctor immediately, telephone your doctor or the Poisons Information Centre (telephone 13 11 26 in Australia, or call 0800 764 766 in New Zealand) for advice, or go to Accident and Emergency at the nearest hospital, or go to Accident and Emergency at the nearest hospital.

You may need urgent medical attention.

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

While you are being given DBL™ Methotrexate Injection

Things you must 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.

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.

Be careful to use an effective method of birth control while you are being treated with DBL™ Methotrexate Injection and for at least 12 weeks after stopping treatment.

A barrier method of birth control, such as a condom, should be used. 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 DBL™ Methotrexate Injection, or for up to 12 weeks 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.

DBL™ Methotrexate Injection may cause your skin to be much more sensitive to sunlight than it is normally. 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.

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.

Things you must not do

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

Alcohol may increase the side effects of DBL™ Methotrexate Injection.

Things to be careful of

Be careful driving or operating machinery until you know how DBL™ Methotrexate Injection affects you.

This medicine 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.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are being given DBL™ Methotrexate Injection.

This medicine may have unwanted side effects. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

Tell your doctor, pharmacist or nurse if you notice any of the following and they worry you:

- mild nausea
- stomach pains
- mild tiredness
- mild chills
- mild dizziness
- drowsiness
- increased burning of the skin from sun exposure
- hair loss (usually occurs only with high doses of methotrexate)
- inflamed mouth gums
- inflamed mucous membranes (mucositis) or sore mouth
- loss of appetite
- changes in menstrual cycle unusual vaginal discharge
- mild headaches
- ringing in the ears
- eye discomfort.

The above list includes side effects which are usually mild or short-lived.

Tell your doctor or nurse as soon as possible if you notice any of the following:

- diarrhoea
- vomiting
- mouth ulcers
- skin rash, itchiness
- difficulty speaking
- back pain
- stiff neck
- painful joints or muscles
- irritability and confusion
- altered conscious state
- painful urination or difficulty urinating, lower back or side pain (these may be symptoms of kidney disease)
- swelling of hands, ankles or feet
- muscle cramps, spasms, weakness or paralysis
- blurred vision or impaired vision.

The above list includes serious side effects, which may require medical attention.

If any of the following happen, tell your doctor or nurse immediately, or go to Accident and Emergency at your nearest hospital:

- 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.
- swollen glands (lymph nodes)
- dry, non-productive cough
- signs of an infection (such as fever, chills, sore throat, cough)
- tiredness, headaches, dizziness and looking pale
- unusual bleeding or bruising (including blood in your stools or urine)
- yellowing of the skin and eyes, nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, and dark coloured urine (these may be symptoms of a type of liver disease called hepatitis)
- chest pain
- seizures (fits)
- skin ulceration or severe skin rash.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor, nurse or pharmacist if you notice anything that is 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 DBL™ Methotrexate Injection may take some time to occur. Therefore even after you have finished your treatment, you should tell your doctor immediately if you notice any of the side effects listed in this section.

After being given DBL™ Methotrexate Injection

Storage

DBL™ Methotrexate Injection will be 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.

Product description

What it looks like

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

Ingredients

DBL™ Methotrexate Injection contains methotrexate as the active ingredient.

It also contains:

- water for injections
- sodium chloride.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

Australian Sponsor:

Hospira Australia Pty Ltd
ABN 58 097 064 330
Level 3
500 Collins Street
Melbourne VIC 3000
Australia

New Zealand Sponsor:

Hospira NZ Limited
58 Richard Pearse Drive
Airport Oaks, Mangere 2022
Auckland
New Zealand

DBL™ Methotrexate Injection comes in the following strengths and pack sizes:

- 5mg/2mL vial x 5 AUST R 16313
- 50mg/2mL vial x 5 AUST R 16314
- 500mg/20mL vial x 1 AUST R 47252
- 1 g/10 mL vial x 1 AUST R 16312

This leaflet was updated in September 2014.