

TREXJECT®

methotrexate (as sodium) solution for injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about TREXJECT.

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 using this medicine against the benefits they expect it will have for you.

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

Keep this leaflet.

You may need to read it again.

What TREXJECT is used for

TREXJECT is used to treat:

- severe psoriasis (a skin disease with thickened patches of red skin, often with silvery scales), and
- severe rheumatoid arthritis (a disease mainly affecting the joints with pain and swelling).

when these conditions do not improve with other medicines.

This medicine contains methotrexate, which belongs to a group of medicines known as antineoplastic medicines. These are medicines used to treat some cancers.

The medicine works by preventing the growth of certain cells.

Your doctor will be able to tell you about the specific condition for which you have been prescribed it.

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

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.

Before you are given TREXJECT

When you must not use it

Do not use this medicine 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.

Do not use this medicine if you:

- have kidney disease or poor kidney function,
- have liver disease or poor liver function,
- are pregnant or if you or your partner is planning to get pregnant,
- are breastfeeding,
- have a problem with your immune system such as severe or repeated infections, e.g. tuberculosis or HIV,
- have any blood disorders, or conditions which cause a reduced

number of red blood cells, white blood cells, or platelets,

- are receiving radiotherapy e.g. X-rays, ultra violet radiotherapy,
- have a stomach ulcer or ulcerative colitis (bleeding from your bowel),
- are an alcoholic,
- have an infection,
- are about to have surgery that involves being put to sleep (anaesthesia).

Do not use live vaccine while you are using TREXJECT.

Do not use this medicine if you are taking acitretin (a medicine to treat psoriasis and other skin conditions).

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you start to use it

Both you and your partner must use a reliable method of contraception (birth control) during and for at least 3 months after treatment with TREXJECT.

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

Tell your doctor if you are pregnant or plan to become pregnant.

TREXJECT may affect your developing baby if used during pregnancy. If it is necessary for you to use it, your doctor or pharmacist will discuss the risks and benefits of using it during pregnancy.

Tell your doctor if you are breastfeeding.

TREXJECT passes into breast milk and should not be used when breastfeeding.

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

- any sort of infection or immune system disorder e.g. sinusitis, tooth abscess, etc.,
- stomach ulcer or ulcerative colitis (bleeding from your bowel),
- fluid or swelling in your abdomen or stomach,
- fever, chills, sore throat or mouth ulcers,
- bleeding or bruising more than usual,
- kidney problems,
- lung problems,
- diabetes,
- folate deficiency,
- tiredness, headaches, shortness of breath, dizziness, looking pale.

If you have not told your doctor about any of the above, tell him/her before using this medicine.

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 TREXJECT may interfere with each other. These include:

- medicine for gastric reflux such as omeprazole and pantoprazole,
- anticancer drugs such as cisplatin, mercaptopurine or asparaginase,
- antibiotics such as tetracyclines and sulphonamides,
- medicine used to relieve swelling and inflammation called non-steroidal anti-inflammatory medicines (NSAIDs) and salicylates such as aspirin and diclofenac,
- medicines for epilepsy such as phenytoin,

- corticosteroids such as hydrocortisone and prednisolone,
- medicines for diabetes such as sulphonylureas,
- medicines that reduce cholesterol such as cholestyramine,
- medicines for gout such as allopurinol and probenecid,
- vitamin preparations that contain folic acid,
- other medicines for rheumatoid arthritis, such as leflunomide and sulfasalazine,
- other medicines for psoriasis such as etretinate,
- medicines for heart problems such as amiodarone,
- medicines used to treat asthma and related compounds such as theophylline,
- antimalarial medicine such as pyrimethamine.

Methotrexate can also be affected by the following:

- blood transfusions,
- nitrous oxide anaesthetics,
- vaccinations,
- alcohol,
- radiation e.g. X-rays, radiotherapy.

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

You should not receive certain vaccinations while being treated with TREXJECT.

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

Your doctor will advise you about continuing to take other medicines while you are being given methotrexate.

You may need different amounts of your medicine, or you may need to use different medicines. Your doctor or pharmacist will advise you.

Your doctor has more information on medicines to be careful with or avoid while using this medicine.

How TREXJECT is given

TREXJECT is usually given by a doctor or nurse as a weekly injection under the skin.

Response to the treatment is usually seen after 4 to 8 weeks.

Your doctor will decide what dose you should be given, 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.

Your doctor may decide that you can administer the injection yourself under the skin (subcutaneously). If you will be self-administering TREXJECT, your doctor or nurse will give you detailed instructions on how to do this. Information is also provided below on how to self-administer the injection.

Instructions for handling:

The following protective recommendations are given due to the toxic nature of this substance:

- personnel should be trained in good handling technique
- pregnant staff should be excluded from working with this drug
- **it is important that you and your caregiver wear disposable gloves when handling methotrexate injection**
- all items used for administration or cleaning, including gloves, should be placed in high-risk, waste disposal bags for high temperature incineration. You should talk to your doctor or pharmacist regarding disposal of these items.
- accidental contact with the skin or eyes should be treated immediately by copious lavage with water or sodium bicarbonate solution; medical attention should be sought.

How much to inject

Your doctor will decide how much TREXJECT you should use.

How to inject

The following instructions explain how to self-inject TREXJECT.

Carefully read the instructions below before starting your injection, and always use the injection technique advised by your doctor, pharmacist or nurse.

For any problem or question, contact your doctor, pharmacist or nurse.

Preparation:

Select a clean, well-lit and flat working surface.

Collect necessary items before you begin:

- 1 TREXJECT pre-filled syringe
- 1 alcohol swab (provided in the packaging)

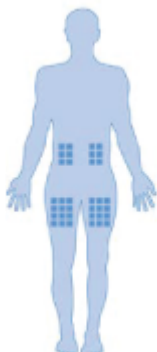
Wash your hands carefully. Before use, check the TREXJECT syringe for visual defects (or cracks).

Injection site

The best areas of skin for injection as shown in the diagram below are the:

- upper thighs, and,
- abdomen except around the navel.

However, obese patients (i.e. patients with a body weight of more than 100 kg) should inject TREXJECT solely in the upper thighs (not in the abdomen).



If someone is helping you with the injection, he/she may also give the injection into the back of your arms, just below the shoulder.

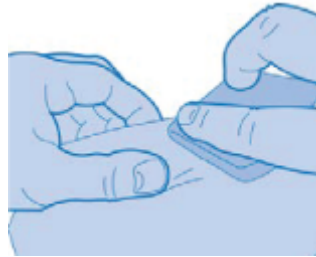
Change the injection site with each injection. This may reduce the risk of

developing irritations at the injection site.

Never inject into skin that is tender, bruised, red, hard, scarred or where you have stretch marks. If you have psoriasis, you should avoid injecting directly into any raised, thick, red or scaly skin patches or lesions.

Injecting the solution:

1. Remove the pre-filled syringe from the packaging at room temperature.
2. Warm the syringe gently in your hands before injecting to avoid pain.
3. Choose an injection site and disinfect it with the alcohol swab provided.
Allow at least 60 seconds for the alcohol to dry.



4. Carefully remove the grey protective plastic cap by pulling it straight off the syringe. If the cap is very stiff, turn it slightly with a pulling movement.

Important: Do not touch the needle of the pre-filled syringe.



5. Using two fingers, pinch up a fold of skin and quickly insert the needle into the skin at a 90-degree angle.



6. Insert the needle fully into the fold of skin. Slowly push the plunger down completely to inject the liquid underneath your skin. Hold the skin securely until the injection is completed. Carefully pull the needle straight out.



Methotrexate should not come into contact with the surface of the skin or mucosa. In the event of contamination, the affected area must be rinsed immediately with plenty of water.

If you or someone around you is injured by the needle, consult your doctor immediately and do not use this pre-filled syringe.

Disposal and other handling:

Keep your syringes and syringe disposal unit out of reach of children; lock the supplies away if possible.

Never re-use syringes or needles.

Always use a sterile (aseptic) technique as described here. If in any doubt, discard needles, syringes or solution and start again.

Always place the used syringes in the appropriate disposal unit.

If you forget to use it

If you have forgotten to give yourself an injection at the right time, do it as soon as you remember and then follow on with the next injection one week later. Do not take a double dose to make up for the forgotten single dose.

Ask your doctor if you are not sure what to do or have trouble remembering to inject your medicine.

Ask your doctor or nurse if you have any questions on how to inject TREXJECT.

If you are given too much (overdose)

This rarely happens as TREXJECT is usually administered under the care of a highly trained doctor. However, if you are given too much methotrexate, you may experience some of the effects listed under “Side effects” below.

If you self-administer too much or too often, contact your doctor or the Poisons Information Centre on 13 11 26 for recommendations on the management and treatment of overdosage.

Your doctor has information on how to recognise and treat an overdose. Ask your doctor if you have any concerns.

If you experience severe side effects, tell your doctor immediately, or go to the nearest hospital emergency department.

While you are using TREXJECT

Things you must do

- **Both you and your partner must use a reliable method of contraception (birth control) during and for at least 3 months after treatment with TREXJECT.**

This is because methotrexate can cause damage to the baby during pregnancy and can also cause genetic problems if the baby is conceived while you are taking TREXJECT.

It is recommended you use some kind of birth control while you using TREXJECT and for at least 3 months after you stop 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.

- **Try to stay out of the sun and do not use sunlamps.**
Methotrexate can increase your sensitivity to sunlight and cause severe reactions.
- **Do not drink any alcohol while you are being treated with TREXJECT, as this may cause permanent liver damage.**
- **Discuss with your doctor how much water or fluids you should have whilst you are using this medicine. Inadequate fluid intake can increase the side effects of this medicine.**
- **Do not drive or operate machinery until you know how methotrexate affects you.**
Methotrexate may cause dizziness or tiredness in some people and therefore may affect alertness.
- **If you can, avoid people with infections.**
Check with your doctor immediately if you think that you are getting an infection or if you get a fever or chills, cough or hoarseness, lower back or side pain, or painful or difficult urination.

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

Tell any other doctors, dentists, pharmacists and nurses who treat you that you are being given this medicine.

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

It may affect other medicines used during surgery.

If you become pregnant while using this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that 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.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are using TREXJECT.

Like other medicines, methotrexate can cause some side effects. If they occur, most are likely to be minor or temporary. However, some may be serious and need medical attention.

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

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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

- Signs of unusual bleeding such as blood in stools or urine, vomiting blood or an increased tendency to bleed, or to develop unusual bruising,
- Signs of an allergic reaction such as swelling of face, lips or tongue, rash, redness, hives, itching, shortness of breath, wheezing or difficulty breathing,
- Pinpoint red spots or painful blistering resulting in peeling of layers of the skin,
- Signs of infection such as fever, chills, sore throat, sweats or feeling generally unwell,
- Signs of liver problems (jaundice or hepatitis) such as lighter patches on skin, yellowing of the skin/eyes, nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, and dark coloured urine (jaundice),
- Severe blisters and bleeding in the lips, eyes, mouth, nose and genitals (Stevens-Johnson syndrome),
- Chest pain,
- Fits.

These are very serious side effects. You may need urgent medical attention or hospitalisation.

All of these side effects are very rare.

Tell your doctor or nurse immediately if you notice any of the following:

- infection of hair roots or hair loss, especially of the scalp,
- frequent or painful urination (cystitis/dysuria), or blood in the urine,
- changes in the menstrual cycle (periods),
- bleeding gums, sore mouth, difficulty swallowing, cold sores, mouth ulcers,
- dry, non-productive cough,
- signs of anaemia such as tiredness, headache, shortness of breath, dizziness or looking pale,
- weakness, numbness or paralysis.

These may be serious side effects. You may need urgent medical attention.

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

- blurred vision,
- ringing in the ears,
- conjunctivitis (itchy eyes and crusty eyelids),
- sensitivity to the sun,
- acne or boils or skin ulcers,
- lack of appetite or weight loss,
- difficulty speaking, writing etc.,
- drowsiness,
- mild nausea or stomach pain, feeling thirsty,
- irritability, depression, confusion or mood changes,
- changes in the toenails or fingernails.

These are the more common side effects of methotrexate.

Other side effects not listed above may also occur in some patients. If you notice any other effects, check with your doctor. Other side effects may only be seen by blood tests.

Your doctor will carry out any necessary tests.

Storage

TREXJECT will usually be stored in the pharmacy or on the ward. The injection is kept in a cool dry place, protected from light, where the temperature stays below 25°C.

If you are self-administering and storing TREXJECT at home, keep it in a cool dry place where the temperature stays below 25°C.

Do not store TREXJECT or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Syringes should NOT be placed in your household recycling bin, waste bin or public litter bin.

Always make sure your used TREXJECT syringes are secured in a strong plastic container or a sharps bin and all items used for administration or cleaning, including gloves, should be placed in high-risk, waste disposal bags before returning to your public hospital or participating pharmacy for disposal in a cytotoxic waste bin.

You should talk to your doctor or pharmacist regarding disposal of these items.

Product description

What it looks like

TREXJECT is a yellow-brown solution in a glass pre-filled syringe.

Ingredients

The active ingredient is methotrexate (as sodium).

TREXJECT also contains:

- sodium chloride
- sodium hydroxide
- water for injections

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

Supplier

Link Medical Products Pty Ltd
5 Apollo Street
Warriewood NSW 2102
Australia
Tel: 1800 181 060

This leaflet was last updated in November 2015.

Australian Register Numbers

7.5 mg/0.15 mL AUST R 233714
10 mg/0.2 mL AUST R 233715
12.5 mg/0.25 mL AUST R 233716
15 mg/0.3 mL AUST R 233717
17.5 mg/0.35 mL AUST R 233718
20 mg/0.4 mL AUST R 233719
22.5 mg/0.45 mL AUST R 233720
25 mg/0.5 mL AUST R 233721