

# Methotrexate Sandoz®

## 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 Methotrexate Sandoz?

Methotrexate Sandoz contains the active ingredient methotrexate (as disodium). Methotrexate Sandoz is used to treat inflammatory conditions, including severe psoriasis, and active rheumatoid arthritis.

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

### 2. What should I know before I use Methotrexate Sandoz?

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

### 3. What if I am taking other medicines?

Some medicines may interfere with Methotrexate Sandoz 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 Methotrexate Sandoz?

- Methotrexate Sandoz is given as a **once weekly** injection under the skin (subcutaneous).
- You may decide together with your doctor on a suitable weekday each week to receive your injection.

More instructions can be found in Section [4. How do I use Methotrexate Sandoz?](#) in the full CMI.

### 5. What should I know while using Methotrexate Sandoz?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using Methotrexate Sandoz.</li><li>• Ensure you and your partner are using a reliable method of contraception during, and at least for six months after treatment with Methotrexate Sandoz.</li><li>• Tell your doctor if you develop an infection or you notice new or changed spots on your skin.</li><li>• Discuss with your doctor, your water and fluid intake. Dehydration can increase the risk of side effects</li><li>• Tell your doctor if you are scheduled for any vaccines.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• You should not receive certain vaccinations while being treated with Methotrexate Sandoz.</li><li>• You should not breastfeeding while using Methotrexate Sandoz.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Do not drive or operate machinery until you know how Methotrexate Sandoz affects you. Methotrexate Sandoz may cause dizziness or tiredness in some people and therefore may affect alertness.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Avoid drinking alcohol while you are being treated with Methotrexate Sandoz, as this may cause permanent liver damage.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store below 25°C. Store in the original package in order to protect from light.</li></ul>

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

### 6. Are there any side effects?

**Side effects that require urgent medical attention include:** Signs of an allergic reaction, such as chest tightness, difficulty breathing, swelling of face lips and tongue, rash; signs suggesting a blood disorder, such as persistent fever, bruising, bleeding, paleness, blood in stools, urine, or vomit; pinpoint red spots or painful blistering resulting in peeling of layers of skin, severe blisters, signs of infection such as fever, chills, sore throat, signs of liver problems such as yellowing of skin, eyes, loss of appetite, itching and dark coloured urine, chest pain, fits; signs of lung damage, such as a dry non-productive cough or shortness of breath. 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

Use of Methotrexate Sandoz is only for severe disease which is not treated adequately by other forms of therapy and only when diagnosis has been made. Due to the risk of fatal or severe reactions to methotrexate, you should be treated under supervision of your doctor or specialist.

Methotrexate can cause severe damage to blood, liver, kidneys, lungs and gastrointestinal system, and may increase your risk of bleeding. This is more likely when methotrexate is used at high or repeated doses. The risk of damage to these body systems will depend on several factors, including your health before starting methotrexate, and other medicines that you take. Serious and potentially fatal infections may occur with methotrexate therapy.

Your doctor will monitor your blood counts, liver function and kidney function while you are using methotrexate.

Tell your doctor immediately if you experience diarrhoea or stomach ulcers, as methotrexate may need to be paused to prevent further bleeding.

If you notice symptoms such as a dry non-productive cough or shortness of breath, stop using methotrexate and talk to your doctor.

Avoid alcohol while using methotrexate.

Tell your doctor if you are taking nonsteroidal anti-inflammatory drugs (NSAIDs), which are medicines used to relieve pain, swelling and inflammation.

Use of methotrexate to treat severe rheumatoid arthritis and psoriasis in children has not been well documented.

Methotrexate has caused foetal death and/or congenital anomalies. It should not be used in pregnant women or in those who might become pregnant. Methotrexate should not be used in the treatment of psoriasis and rheumatoid arthritis in pregnant women. Methotrexate should not be started until it is confirmed you are not pregnant, and due to the serious risk to the foetus you should not become pregnant while undergoing treatment.

Pregnancy should be avoided if either partner is receiving methotrexate, during and for a minimum of 6 months after therapy has ceased.

**Methotrexate Sandoz should be used once a week on the same day each week.** Taking Methotrexate Sandoz more frequently than once each week may cause life-threatening or fatal toxicity. If you are unsure of how you should take Methotrexate Sandoz, talk to your doctor or pharmacist.

# Methotrexate Sandoz®

**Active ingredient(s):** *methotrexate (as sodium)*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Methotrexate Sandoz. **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 Sandoz.**

**Where to find information in this leaflet:**

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

## 1. Why am I using Methotrexate Sandoz?

**Methotrexate Sandoz contains the active ingredient methotrexate (as sodium).** Methotrexate belongs to a group of medicines known as immunosuppressants. Methotrexate works by preventing the growth of certain cells.

Methotrexate Sandoz is used to treat:

- **Active rheumatoid arthritis (RA)** in adult patients where treatment with disease modifying antirheumatic drugs (DMARDs) is indicated.
- **Polyarthritic forms (when five or more joints are involved) of severe, active, juvenile idiopathic arthritis (JIA)** when the response to non-steroidal anti-inflammatory drugs (NSAIDs) has been inadequate
- **Severe forms of psoriasis** particularly of the plaque type, which cannot be sufficiently treated with conventional therapy such as phototherapy, PUVA, and retinoids, and severe psoriasis affecting the joints (psoriatic arthritis)

## 2. What should I know before I use Methotrexate Sandoz?

### Warnings

#### Do not use Methotrexate Sandoz 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.
- have liver disease or poor liver function
- are an alcoholic
- have kidney disease or poor kidney function
- have any blood disorders, or conditions which cause a reduced number of red blood cells, white blood cells or platelets.
- have problems with your immune system such as severe or repeated infections, e.g. tuberculosis or HIV
- have an infection
- have a stomach ulcer or ulcerative colitis (bleeding from your bowel)
- are pregnant, or if you or your partner are planning to get pregnant
- are breastfeeding
- have poor nutritional status, such as malnutrition
- are about to have surgery that involves general anaesthetic
- are taking a retinoid such as acitretin (a medicine used to treat skin conditions including psoriasis)

Do not receive a live vaccine while you are using Methotrexate Sandoz.

#### Check with your doctor if you:

- have any sort of infection or immune system disorder e.g. sinusitis, tooth abscess etc.
- have a stomach ulcer or ulcerative colitis (bleeding from the bowel)
- have fluid or swelling in your abdomen or stomach
- have fever, chills, sore throat or mouth ulcers
- have any increased or unusual bleeding or bruising
- have kidney problems
- have lung problems
- have diabetes
- have a folate deficiency
- are experiencing tiredness, headaches, shortness of breath, dizziness, or if you are pale
- are receiving radiotherapy e.g. X-rays, ultraviolet radiotherapy

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.

If you wish to become pregnant you should consult your doctor, who may refer you for specialist advice before the planned start of treatment. You and your partner must

avoid becoming pregnant, and use a reliable method of contraception during, and for at least 6 months after treatment with Methotrexate Sandoz. The possibility of pregnancy must be excluded e.g. pregnancy test prior to starting treatment with Methotrexate Sandoz.

Methotrexate Sandoz passes into breast milk. Stop breastfeeding prior to, and during treatment with Methotrexate Sandoz.

### Use in liver impairment

- Where possible, it is recommended that Methotrexate Sandoz is not used where there is impaired liver function, or liver disorders, including where alcoholism is present.

### Use in kidney impairment

- Where possible, it is recommended that Methotrexate Sandoz is not used where there is decreased kidney function.

### Use in the elderly

- Elderly patients are more likely to have decreased liver and kidney function, and decreased folate levels. Lower doses may need to be considered, and increased monitoring may be required.

### Monitoring and follow up

To check you are receiving the correct dose, and to detect any severe side effects, your doctor may carry out checkups and laboratory tests from time to time. These tests may include:

- Examinations of the mouth and throat for any changes in the mucosa
- Blood tests/ blood count with number of blood cells
- Blood tests to monitor liver function
- Imaging tests to monitor condition
- Small sample of tissue taken from the liver in order to examine it more closely (biopsy)
- Blood tests to monitor kidney function
- Lung function tests and respiratory tract monitoring

If you, your partner or your caregiver notice new onset or worsening of neurological symptoms including general muscle weakness, disturbance of vision, changes in thinking, memory and orientation leading to confusion and personality changes contact your doctor immediately because these may be symptoms of a very rare, serious brain infection called progressive multifocal leukoencephalopathy (PML).

## 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.

The concurrent use of Methotrexate Sandoz and some other medicines may interfere with each other, including (but not limited to):

- Retinoids such as acitretin (a medicine used to treat skin conditions including psoriasis)
- Medicines for gastric reflux such as omeprazole and pantoprazole
- Anticancer drugs such as cisplatin, mercaptopurine or asparaginase
- Antibiotics such as trimethoprim, tetracyclines and sulphonamides
- Non-steroidal anti-inflammatory drugs or salicylates (medicines used to relieve pain, swelling and inflammation such as aspirin, diclofenac and ibuprofen)
- Medicines for epilepsy such as phenytoin and sodium valproate
- Corticosteroids such as hydrocortisone and prednisone
- 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
- Other immunosuppressive medication

**Methotrexate Sandoz may also be affected by, or interfere with, the following:**

- Blood transfusions
- Nitrous oxide anaesthetics
- Vaccinations
- Alcohol
- Radiation e.g. X-rays, 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 Methotrexate Sandoz.**

## 4. How do I use Methotrexate Sandoz?

### How much to use

- Your doctor will decide what dose you should be given, when it should be given, and for 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 other medicines are being given at the same time.
- Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
- Too much Methotrexate Sandoz may be fatal.

### When to Use Methotrexate Sandoz

- Methotrexate Sandoz is given as a **once weekly** injection under the skin (subcutaneous), into a muscle or a vein, in children and adolescents it must not be given intravenously for the treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriasis vulgaris and psoriatic arthritis.
- You may decide together with your doctor on a suitable weekday each week to receive your injection.

### How to use Methotrexate Sandoz

Methotrexate Sandoz is usually given by a doctor or nurse as a **once weekly** injection under the skin, into a muscle or a vein.

- Your doctor may decide that you can administer the injection yourself under the skin (subcutaneously). If you will be self-administering Methotrexate Sandoz, 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.

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 not handle or administer this drug
- **it is important that you and your caregiver wear disposable gloves when handling methotrexate injection**
- 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

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

Injection site:

The best sites for injection are the:

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

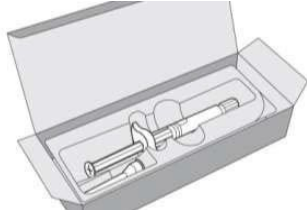


Change the injection site with each injection. This may reduce the risk of developing irritations at the injection site.

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:**

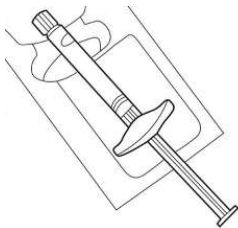
Open the box and read the package leaflet carefully.



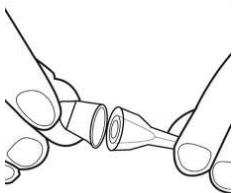
- Take out the inner-package, containing the pre-filled syringe and cannula package.
- Open the inner-package by pulling the corner flap. Take out the pre-filled syringe.
- Remove (twist) the grey rubber cap from the syringe, without touching the opening of the pre-filled syringe.



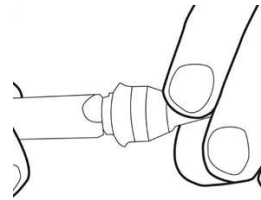
- Place the syringe back into the inner-package. The yellow solution will be unable to escape.



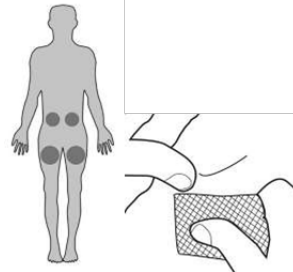
- Now, open the cannula packaging by pulling the flap. Do not touch the round sterile opening. To avoid this, keep hold of the bottom end of the cannula packaging.



- Attach the cannula, with its packaging, onto the syringe and fix it (clockwise). Put the syringe in a readily accessible place.



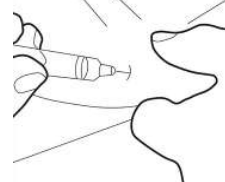
- Choose an injection site. Wipe the injection site with the alcohol pad, using a circular motion. Do not touch this area before injecting.



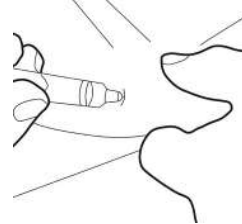
- Pull the packaging from the cannula. Put aside the cannula packaging.



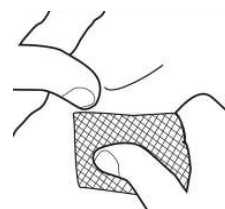
- Do not touch the sterile cannula. If this should happen, ask your doctor or pharmacist about using of another cannula. With two fingers, form a skin fold and puncture it almost vertically.



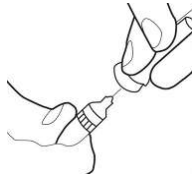
- Push the cannula completely into the skin fold. Then, slowly push the plunger down and inject all the fluid underneath the skin.



- Carefully remove the cannula and dab the injection site with a swab. Do not rub, as this will cause irritation at the injection site.



- To avoid any injuries, carefully put the cannula packaging back on to the cannula by gently pressing it into place.



**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 Methotrexate Sandoz**

Methotrexate Sandoz should be used **once weekly** at the same time each week. If you miss your dose at the usual time, do it as soon as you remember and then follow on with the next injection one week later.

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Do not take a double dose to make up for the dose you missed.**

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

**If you use too much Methotrexate Sandoz**

If you think that you have used too much Methotrexate Sandoz, you may need urgent medical attention.

**You should immediately:**

- phone the National Poisons Centre (by calling 0800 POISON (0800 764766)), 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 Methotrexate Sandoz?**

**Driving or using machines**

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 .

**Drinking alcohol**

Avoid drinking alcohol while you are being treated with Methotrexate Sandoz, as this may cause permanent liver damage.

**Looking after your medicine**

Follow the instructions in the carton on how to take care of your medicine properly.

Store below 25°C in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

**When to discard your medicine**

Methotrexate Sandoz is a single use injection for use in one patient on one occasion only Once opened, use immediately.

**Getting rid of any unwanted medicine**

Methotrexate Sandoz should NOT be placed in your household recycling bin, waste bin or public litter bin. Always make sure your used Methotrexate Sandoz syringes are secured in a strong plastic container, or a sharps bin before returning to your public hospital or participating pharmacy for disposal in a cytotoxic waste bin.

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

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.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

**Less serious side effects**

Less serious side effects	What to do
<b>Gut and digestion:</b> <ul style="list-style-type: none"> <li>• Inflammation of the mouth lining</li> <li>• Indigestion</li> <li>• Feeling sick</li> <li>• Loss of appetite or weight loss</li> <li>• Abdominal pain</li> </ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>
<b>Skin and nails:</b> <ul style="list-style-type: none"> <li>• Rash</li> <li>• Reddening of the skin</li> </ul>	

<ul style="list-style-type: none"> <li>• Itching</li> <li>• Sensitivity to the sun</li> <li>• Acne, boils or skin ulcers</li> <li>• Changes in the toenails or fingernails</li> </ul> <p><b>Mental state:</b></p> <ul style="list-style-type: none"> <li>• Irritability</li> <li>• Depression</li> <li>• Confusion</li> <li>• Mood changes</li> </ul> <p><b>Signs of anaemia such as:</b></p> <ul style="list-style-type: none"> <li>• Tiredness</li> <li>• Headache</li> <li>• Shortness of breath</li> <li>• Dizziness</li> <li>• Looking pale</li> </ul>	
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<p><b>Signs of liver problems (jaundice or hepatitis) such as:</b></p> <ul style="list-style-type: none"> <li>• Lighter patches on skin</li> <li>• Yellowing of the skin/eyes</li> <li>• Nausea, vomiting</li> <li>• Loss of appetite</li> <li>• Feeling generally unwell</li> <li>• Fever</li> <li>• Itching</li> <li>• Dark coloured urine (jaundice)</li> </ul> <p><b>Signs of kidney problems such as:</b></p> <ul style="list-style-type: none"> <li>• Swelling of the hands, ankles, or feet</li> <li>• Changes to the frequency of urination</li> <li>• Absence of urination</li> </ul> <p><b>Signs of lung problems such as:</b></p> <ul style="list-style-type: none"> <li>• Chest pain</li> <li>• Shortness of breath</li> <li>• Fever</li> <li>• Persistent dry non-productive cough</li> <li>• Spitting or coughing blood</li> </ul> <p><b>Signs of a blood clot such as:</b></p> <ul style="list-style-type: none"> <li>• Weakness of one side of the body</li> <li>• Pain, swelling, redness and unusual warmth in one of your legs</li> </ul>	
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## Serious side effects

Serious side effects	What to do
<p><b>Gut and digestion:</b></p> <ul style="list-style-type: none"> <li>• Mouth ulcers</li> <li>• Diarrhoea</li> </ul> <p><b>Signs of unusual bleeding such as:</b></p> <ul style="list-style-type: none"> <li>• Blood in stools or urine</li> <li>• Vomiting blood</li> <li>• An increased tendency to bleed</li> <li>• Unusual bruising</li> </ul> <p><b>Signs of an allergic reaction such as:</b></p> <ul style="list-style-type: none"> <li>• Swelling of the face, lips or tongue</li> <li>• Rash</li> <li>• Redness</li> <li>• Hives</li> <li>• Itching</li> <li>• Shortness of breath, wheezing or difficulty breathing</li> </ul> <p><b>Signs of a severe skin reaction such as:</b></p> <ul style="list-style-type: none"> <li>• Pinpoint red spots</li> <li>• Painful blistering resulting in peeling of layers of the skin</li> <li>• Severe blisters and bleeding in the lips, eyes, mouth, nose and genitals (Stevens Johnson syndrome)</li> </ul> <p><b>Signs of infection such as:</b></p> <ul style="list-style-type: none"> <li>• Fever, chills, sweats</li> <li>• Sore throat, difficulty swallowing</li> <li>• Feeling generally unwell</li> <li>• Bleeding gums</li> <li>• Mouth ulcers, cold sores</li> </ul>	<p><b>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.</b></p>

**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.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to <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.

### What Methotrexate Sandoz contains

<b>Active ingredient (main ingredient)</b>	Methotrexate (as sodium)
<b>Other ingredients (inactive ingredients)</b>	Sodium chloride Sodium hydroxide Water for injections

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

### **What Methotrexate Sandoz looks like**

Methotrexate Sandoz is solution for injection available in pre-filled syringes as a clear, yellowish solution for injection.

Each box contains pre-filled syringes with 0.375mL, 0.5mL, 0.625mL, 0.75mL, 0.875mL, 1mL, 1.125mL, 1.25mL, 1.375mL, 1.5mL or 2mL solution for injection, single-use injection needles and alcohol pads.

Each box may contain 1, 4, 5, 6 or 12 pre-filled syringes.

\*Not all pack sizes may be marketed.

### **Who distributes Methotrexate Sandoz**

Novartis New Zealand Limited

PO Box 99102, Newmarket,

Auckland 1149

Telephone: 0800 354 335

This leaflet was revised in January 2023.