Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Metronidazole Sandoz IV.

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 Metronidazole Sandoz IV 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 with the medicine.

You may need to read it again.

What Metronidazole Sandoz IV is used for

The name of your medicine is Metronidazole Sandoz IV. It contains the active ingredient metronidazole.

Metronidazole Sandoz IV is an antimicrobial agent used to treat infections in different parts of the body caused by certain micro-organisms.

Metronidazole Sandoz IV is also used to prevent infections before, during and after surgery.

Metronidazole Sandoz IV belongs to a group of antimicrobials called nitroimidazoles. These antimicrobials work by killing the microorganisms that are causing your infection.

Your doctor may have prescribed Metronidazole Sandoz IV for another reason. Ask your doctor if you have any questions about why Metronidazole Sandoz IV has been prescribed for you.

Metronidazole Sandoz IV is available only with a doctor's prescription.

Metronidazole Sandoz IV is not addictive.

Before you are given Metronidazole Sandoz IV

When you must not be given it

Do not use Metronidazole Sandoz IV if:

- you have an allergy to metronidazole, any other nitroimidazoles or any of the ingredients listed at the end of this leaflet Some of the symptoms of an allergic reaction may include wheezing, shortness of breath, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, skin rash, itching or hives.
- 2. you have or have ever had a blood disorder
- 3. you have a disease of the brain, spinal cord or nerves

Do not use Metronidazole Sandoz IV if the packaging is torn or shows signs of tampering.

Do not use Metronidazole Sandoz IV after the expiry date on the pack has passed.

If you are not sure whether you should be given Metronidazole Sandoz IV, talk to your doctor or nurse.

Before you are given it

Tell your doctor if:

- 1. you have any allergies to:
- any other medicines
- any other substances, such as foods, preservatives or dyes

2. you are pregnant, or intend to become pregnant.

Metronidazole Sandoz IV may affect your developing baby if you use it during pregnancy. Your doctor will discuss the risks and benefits of using Metronidazole Sandoz IV during pregnancy.

you are breast-feeding or intend to breastfeed.

Metronidazole Sandoz IV passes into breast milk and may affect your baby. The use of Metronidazole Sandoz IV is not recommended while breast-feeding. Your doctor will discuss the risks and benefits of using it when breast-feeding.

- 4. you are on a low sodium diet
- 5. you drink alcohol

Do not drink alcohol during, (and for one day after stopping), treatment with Metronidazole Sandoz IV

- 6. you have or have had any medical conditions, including:
- kidney problems
- liver problems
- · cardiac problems
- central nervous system diseases
- Crohn's disease, an inflammatory disease of the intestines

If you have not told your doctor about any of the above, tell them before you are given Metronidazole Sandoz IV.

Taking other medicines

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

Some medicines may interfere with Metronidazole Sandoz IV. These include:

- medicines used to prevent blood clots such as warfarin
- disulfiram, a medicine used to treat alcoholism
- some anticancer medicines such as flurouracil or cyclophosphamide
- lithium, a medicine used to treat some types of depression
- corticosteroids such as prednisone or cortisone
- · cimetidine, a medicine used to treat ulcers
- phenobarbitone, a medicine to treat convulsions or for sedation
- phenytoin, a medicine used to treat convulsions
- azathioprine, a medicine used to suppress the immune system
- busulfan, a medicine used to treat some kinds of leukemia and certain other blood disorders

These medicines may be affected by Metronidazole Sandoz IV, or may affect how well it works. You may need to use different amounts of your medicine, or you may need to use different medicines. Your doctor will advise you.

Talk to your doctor about the need for an additional method of contraception while using Metronidazole Sandoz IV.

Some antibiotics may decrease the effectiveness of some birth control pills.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using Metronidazole Sandoz IV.

How Metronidazole Sandoz IV is given

Metronidazole Sandoz IV must only be given by a doctor or nurse.

Metronidazole Sandoz IV is given as a slow injection into a vein.

Your doctor will decide what dose and how long you will receive Metronidazole Sandoz IV. This depends on your condition and whether you are using any other medicines. Metronidazole Sandoz IV is usually given in divided doses throughout the day.

If you are given too much (overdose)

In the unlikely event of an overdose, the doctor treating you will know what to do.

If you are given too much Metronidazole Sandoz IV you may experience symptoms such as vomiting or disorientation.

Contact Poisons Information Centre (phone 13 11 26).

While you are given Metronidazole Sandoz IV

Things you must do

If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.

If you get severe diarrhoea tell your doctor, pharmacist or nurse immediately. Do this even if it occurs several weeks after Metronidazole Sandoz IV has been stopped.

Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any diarrhoea medicine without first checking with your doctor.

If you get a sore white mouth or tongue while using or soon after stopping Metronidazole Sandoz IV, tell your doctor. Also tell your doctor if you get vaginal itching or discharge. This may mean you have a fungal infection called thrush. Sometimes the use of Metronidazole Sandoz IV allows fungi to grow and the above symptoms to occur. Metronidazole Sandoz IV does not work against fungi.

If you become pregnant while you are being treated with Metronidazole Sandoz IV tell your doctor immediately.

If you are using Metronidazole Sandoz IV for 10 days or longer, make sure you have any tests of your blood and nervous system that your doctor may request.

If you are about to start using any new medicine, tell your doctor and pharmacist that you are being treated with Metronidazole Sandoz IV.

If you have to have any blood tests tell your doctor you are being given Metronidazole Sandoz IV.

Metronidazole Sandoz IV may affect the results of some blood tests.

Tell all the doctors, dentists and pharmacists who are treating you that you are using Metronidazole Sandoz IV.

Things you must not do

Do not drink any alcohol or any alcoholic drinks while using (and for at least one day after stopping) Metronidazole Sandoz IV.

The use of alcohol with Metronidazole Sandoz IV may make you feel sick, vomit or have stomach cramps, headaches or flushing.

Do not give Metronidazole Sandoz IV to anyone else, even if they have the same condition as you.

Do not use Metronidazole Sandoz IV to treat any other complaints unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how Metronidazole Sandoz IV affects you.

Metronidazole Sandoz IV may cause dizziness, confusion, hallucination, convulsions or transient visual disorders in some people. Make sure you know how you react to Metronidazole Sandoz IV before you drive a car, operate machinery or do anything else that may be dangerous if you are affected.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are being given Metronidazole Sandoz IV.

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.

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

While using Metronidazole Sandoz IV
Tell your doctor or nurse if you notice any of

- the following and they worry you:oral thrush white, furry, sore tongue and
- vaginal thrush sore and itchy vagina sometimes with a white discharge
- · pain, swelling or redness at the injection site
- diarrhoea

mouth

- nausea (feeling sick), vomiting or abdominal discomfort
- loss of appetite
- · headache or dizziness
- abdominal pain
- dry mouth
- metallic or unpleasant taste in the mouth
- nasal congestion

These side effects are usually mild.

Tell your doctor or nurse immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- severe abdominal cramps or stomach cramps
- watery and severe diarrhoea, which may also be bloody
- allergic reactions which can cause shortness of breath or difficulties breathing, wheezing
- skin rash, itching, hives
- tremors
- fits or seizures
- swelling of the face, lips, tongue, mouth or throat which may cause difficulty in swallowing or breathing may be associated with hypersensitivity reaction and to discontinue the drug at the first sign of a skin rash

- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers
- · darkening of urine
- pain when passing urine or passing more urine than normal
- yellowing of the skin may be associated with hepatitis
- clumsiness, lack of co-ordination, weakness
- · confusion, irritability, depression
- numbness, 'pins and needles'
- · ringing in the ears
- vision disorders

These are very serious side effects. You may need urgent medical attention. Serious side effects are rare.

After finishing Metronidazole Sandoz IV

Tell your doctor immediately if you notice any of the following side effects, even if they occur several weeks after stopping treatment with Metronidazole Sandoz IV:

- · severe abdominal cramps or stomach cramps
- watery and severe diarrhoea, which may also be bloody
- fever, in combination with one or both of the above

These are rare but serious side effects. You may have a serious condition affecting your bowel. Therefore, you may need urgent medical attention. However, this side effect is rare.

Do not take any diarrhoea medicine without first checking with your doctor.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else making you feel unwell. Do not be alarmed by this list of possible side effects. You may not experience any of them.

Storage

Metronidazole Sandoz IV will be stored in the pharmacy or on the ward.

Metronidazole Sandoz IV in glass bottles is kept in a cool dry place, where the temperature stays below 30°C. Metronidazole Sandoz IV in bags is kept in a cool dry place, where the temperature stays below 25°C.

Product description

What it looks like

Metronidazole Sandoz IV is a pale yellow to colourless clear solution. It is available in glass vials and infusion bags in packs of 1, 5 or 10.

Ingredients

Active ingredient

Each Metronidazole Sandoz IV vial or infusion bag contains 500 mg metronidazole.

Inactive ingredients

Metronidazole Sandoz IV also contains the following inactive ingredients:

- citric acid monohydrate
- · dibasic anhydrous sodium phosphate
- sodium chloride
- · water for injections

Metronidazole Sandoz IV does not contain gluten, lactose, sucrose, tartrazine or any other azo dves

SUPPLIER

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This leaflet was revised in August 2013.

Australian Register Number:

 Metronidazole Sandoz IV 500mg/100mL Bag AUST R 118321