

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about Metronidazole-Claris

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-Claris 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- Claris is used for

The name of your medicine is Metronidazole-Claris. It contains the active ingredient metronidazole.

Metronidazole-Claris is an antimicrobial agent used to treat infections in different parts of the body caused by certain microorganisms.

Metronidazole-Claris is also used to prevent infections before, during and after surgery.

Metronidazole-Claris 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-Claris for another reason. Ask your doctor if you have any questions about why Metronidazole - Claris has been prescribed for you.

Metronidazole Claris is available only with a doctor's prescription.

Metronidazole - Claris is not addictive.

### Before you are given Metronidazole-Claris

#### *When you must not be given it*

**Do not use Metronidazole - Claris if:**

1. **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 - Claris if the packaging is torn or shows signs of tampering.**

**Do not use Metronidazole - Claris after the expiry date on the pack has passed.**

**If you are not sure whether you should be given Metronidazole Claris, 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 - Claris may affect your developing baby if you use it during pregnancy. Your doctor will discuss the risks and benefits of using Metronidazole - Claris during pregnancy.
  3. **you are breast-feeding or intend to breast-feed.**

Metronidazole - Claris passes into breast milk and may affect your baby. The use of Metronidazole - Claris 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 - Claris
  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 - Claris**

#### *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 - Claris. 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
- cyclosporin, a medicine used to prevent rejection of transplants
- 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

These medicines may be affected by Metronidazole -Claris, 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 - Claris**

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 - Claris

### How Metronidazole - Claris is given

Metronidazole - Claris must only be given by a doctor or nurse.

Metronidazole - Claris is given as a slow injection into a vein.

Your doctor will decide what dose and how long you will receive Metronidazole - Claris. This depends on your condition and whether you are using any other medicines. Metronidazole - Claris 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 - Claris you may experience symptoms such as vomiting or disorientation. Contact Poisons Information Centre (phone 13 11 26).

### While you are using Metronidazole - Claris

#### *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 - Claris 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 Claris, 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 - Claris allows fungi to grow and the above symptoms to occur. Metronidazole - Claris does not work against fungi.

**If you become pregnant while you are being treated with Metronidazole - Claris tell your doctor immediately.**

**If you are using Metronidazole - Claris 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 - Claris**

**If you have to have any blood tests tell your doctor you are being given Metronidazole - Claris**

Metronidazole - Claris may affect the results of some blood tests.

**Tell all the doctors, dentists and pharmacists who are treating you that you are using Metronidazole - Claris**

*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 - Claris**

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

**Do not give Metronidazole - Claris to anyone else, even if they have the same condition as you.**

**Do not use Metronidazole - Claris 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 - Claris affects you.**

Metronidazole - Claris may cause dizziness in some people. Make sure you know how you react to Metronidazole - Claris before you drive a car, operate machinery or do anything else that may be dangerous if you are affected.

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**Side effects**

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**Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are being given Metronidazole - Claris**

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 - Claris*

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

- oral thrush – white, furry, sore tongue and mouth
- vaginal thrush – sore and itchy vagina sometimes with a white discharge
- pain, swelling or redness at the injection site
- diarrhoea
- 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 coordination, 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 - Claris*

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

- 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.

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**Storage**

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Metronidazole - Claris will be stored in the pharmacy or on the ward.

Metronidazole - Claris is to be kept in a cool dry place, where the temperature stays below 25°C.

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**Product description**

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*What it looks like*

Metronidazole - Claris 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 - Claris vial or infusion bag contains 500 mg metronidazole.

Inactive ingredients

Metronidazole - Claris also contains the following inactive ingredients:

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

Metronidazole - Claris does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

**SPONSOR**

Metronidazole - Claris is supplied in Australia by:

Claris Lifesciences (Aust) Pty Ltd.,  
Suite1, Level 1, 127-133 Burwood  
Road, Burwood,  
NSW 2134

Distributed by:

AFT Pharmaceuticals Pty Ltd  
113 Wicks Road  
North Ryde  
NSW 2113

AFT Pharmaceuticals Ltd.,  
Auckland  
New Zealand

*Australian Registration Number:*

Metronidazole - Claris Vial AUST R 165161

Metronidazole - Claris Bag AUST R 165164

*Date of preparation:*

31 July 2015