

# Miro-Amoxicillin

Amoxicillin 250 mg and 500 mg capsules

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## What is in this leaflet

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Please read this leaflet carefully before you start using Miro-Amoxicillin.

This leaflet answers some common questions about Miro-Amoxicillin. 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 Miro-Amoxicillin 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.

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## What Miro-Amoxicillin is used for

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Miro-Amoxicillin contains penicillin called amoxicillin (as trihydrate) as the active ingredient. Miro-Amoxicillin belongs to a group of medicines called penicillins.

Miro-Amoxicillin is used to treat a range of infections caused by bacteria. These may be infections of the chest (pneumonia), tonsils (tonsillitis), sinuses (sinusitis), urinary and genital tract, skin and fleshy tissues.

Miro-Amoxicillin works by killing the bacteria that cause these infections. Miro-Amoxicillin can also be used to prevent infection.

Your doctor may have prescribed Miro-Amoxicillin for another reason.

Ask your doctor if you have any questions about why Miro-Amoxicillin has been prescribed for you.

Miro-Amoxicillin is available only with a doctor's prescription.

There is no evidence that Miro-Amoxicillin is addictive.

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## **Before you use Miro-Amoxicillin**

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### ***When you must not use it***

Do not use Miro-Amoxicillin if:

- you are allergic to penicillin or similar types of antibiotics such as cephalosporins. If you have ever had an allergic reaction (such as a rash) when taking an antibiotic you should tell your doctor before you take Miro-Amoxicillin.
- you have ever had an allergic reaction to amoxicillin or any of the ingredients listed toward the end of this leaflet. (See "Ingredients")
- the expiry date (EXP) printed on the pack has passed.
- the packaging is torn or shows signs of tampering.

If you are not sure whether you should start using Miro-Amoxicillin, talk to your doctor.

### ***Before you start to use it***

Tell your doctor if

- you are allergic to foods, dyes, preservatives or any other medicines.
- you have ever had an allergic reaction (such as a rash) to any antibiotics in the past.
- you have glandular fever (mononucleosis) or a blood disorder.
- you are pregnant or think you may be pregnant or are breast feeding. *Miro-Amoxicillin may be used during pregnancy (Australian Use in Pregnancy Category A). Miro-Amoxicillin can pass to your baby from breast milk.*
- you have liver or kidney problems. *The dosage of Miro-Amoxicillin may need to be changed or you may need to be given an alternative medicine.*

If you have not told your doctor about any of the above, tell them before you start using Miro-Amoxicillin.

### ***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.

You should also tell any health professional who is prescribing a new medication for you that you are taking Miro-Amoxicillin.

Some medicines may interfere with Miro-Amoxicillin. These include:

- medicines used to treat gout e.g. probenecid or allopurinol.
- the contraceptive pill. *As with other antibiotics, you may need to use extra birth control methods e.g. condoms.*
- other antibiotics. *These may interfere with the actions of Miro-Amoxicillin.*
- Anticoagulants (used to prevent blood clots) such as warfarin.

*These medicines may be affected by Miro-Amoxicillin, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.*

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Miro-Amoxicillin.

**If you have not told your doctor about any of these things, tell them before you take any Miro-Amoxicillin.**

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## **How to use Miro-Amoxicillin**

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Follow your doctor's instructions about how and when to take Miro-Amoxicillin. Your doctor will advise how many doses are needed each day, and for how long you will need to take Miro-Amoxicillin.

Please read the direction label carefully. If you have any concerns about how to take Miro-Amoxicillin, talk to your doctor or pharmacist.

### ***How much to take***

Take Miro-Amoxicillin as directed by your doctor or pharmacist.

The usual dose of Miro-Amoxicillin is one dose taken three times a day. If your doctor has prescribed the Miro-Amoxicillin 3g sachet, this is taken as a single dose.

Swallow Miro-Amoxicillin 250mg and 500mg capsules whole with a glass of water.

### ***When to take it***

Space the doses as evenly as possible throughout the day. For example, if you are taking Miro-Amoxicillin three times a day, take a dose about every eight hours.

Miro-Amoxicillin can be taken with or without food. *The effects of Miro-Amoxicillin are not changed by food.*

### ***How long to take it***

Keep taking Miro-Amoxicillin until the course is finished or for as long as your doctor tells you.

*Do not stop taking Miro-Amoxicillin just because you feel better as the infection can return.*

Do not stop taking Miro-Amoxicillin, or change the dose without first checking with your doctor.

### ***If you forget to take it***

If you forget to take a dose of Miro-Amoxicillin, take it as soon as you remember. Then go back to taking it as directed by your doctor.

Do not take a double dose to make up for the dose that you have missed. Do not take two doses within an hour or so of each other. *Taking more than the prescribed dose can increase the chance of unwanted side effects.*

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## **While you are using Miro-Amoxicillin**

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### ***Things you must do***

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.

Otherwise, your doctor may think that it was not working as it should and change your treatment unnecessarily.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Miro-Amoxicillin.

*Some medicines may affect the way other medicines work.*

If you develop itching, swelling or a skin rash when you are taking Miro-Amoxicillin, do not take any more Miro-Amoxicillin and tell your doctor at once.

If you develop severe diarrhoea when taking Miro-Amoxicillin tell your doctor as soon as possible. Do not take any medication to stop the diarrhoea (e.g. Lomotil or Imodium).

### ***Things you must not do***

Do not give Miro-Amoxicillin to anyone else, even if they have the same condition as you.

Do not use Miro-Amoxicillin to treat any other complaints unless your doctor says to.

### ***Things to be careful of***

Be careful driving or operating machinery until you know how Miro-Amoxicillin affects you.

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## **In case of overdose**

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### ***If you take too much (overdose)***

**If you (or someone else) has taken a large amount of Miro-Amoxicillin all at once, give plenty of water to drink and immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Miro-Amoxicillin.**

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you are not sure what to do, contact your doctor, pharmacist or nearest hospital.

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## **Side Effects**

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Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Miro-Amoxicillin.

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

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

### **MILD EFFECTS**

- **Tell your doctor if you notice any of the following that are troublesome or on going:**

- diarrhoea (several loose bowel movements per day), indigestion, feeling sick or being sick.
- soreness of the mouth or tongue
- overgrowth of yeast infections (thrush).

### **MORE SERIOUS EFFECTS**

- **Tell your doctor immediately if you notice any of the following:**
  - itching, rash
  - unusual bleeding or bruising
  - yellowing of the skin or eyes
  - dark urine or pale stools
  - difficulty or pain on passing urine.
  - severe diarrhoea.
- **Stop taking Miro-Amoxicillin and contact your doctor or go to the emergency department of your nearest hospital if any of the following happens:**
  - Wheezing, swelling of the lips/mouth, difficulty in breathing, hay fever, lumpy rash (hives) or fainting. These could be symptoms of an allergic reaction.

Remember you should tell your doctor or pharmacist as soon as possible if any of these, or any other unusual events or problems occur during or after treatment with Miro-Amoxicillin.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

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

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## **After using Miro-Amoxicillin**

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### ***Storage***

Keep your medication in the pack until it is time to take them.

Keep this medicine where children cannot reach it, such as in a locked cupboard.

Keep the pack in a cool dry place where the temperature stays below 30°C. Do not leave it in the car on a hot day. Do not store medicine in the bathroom or near a sink. Heat and dampness can destroy some 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.

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## Product description

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### ***What it looks like***

Miro-Amoxicillin come in two strengths:

- Miro-Amoxicillin Capsules 250 mg
- Miro-Amoxicillin Capsules 500 mg

Capsules:

Amoxicillin 250 mg Capsules : Red / Buff coloured size '2' capsules containing white to off white powder printed with 'AMOXY 250' in black ink.

Amoxicillin 500 mg Capsules : Red / Buff Coloured size '0' Capsules containing white to off white powder printed with 'AMOXY 500 ' in black ink

### Active ingredient:

Each Filled capsule contains Amoxicillin Trihydrate BP/EP equivalent to Amoxicillin 250 mg.

Each Filled capsule contains Amoxicillin Trihydrate BP/EP equivalent to Amoxicillin 500 mg.

### Inactive ingredients:

Each capsule contains:

Croscarmellose Sodium , Magnesium stearate.

### Capsule shell components:

#### **Cap:**

Brilliant blue E133

Carmoisine E122

Sunset yellow E110

Titanium dioxide E171

#### **Body:**

Quinoline yellow E104  
Sunset yellow E110  
Titanium dioxide E171

**Shell composition:**

Purified Water  
Methyl Parahydroxybenzoate E218  
Propyl Parahydroxybenzoate E216  
Gelatin (TSE Free)  
Sodium lauryl sulphate

Printing ink components:

Absolute alcohol  
Isopropyl alcohol  
Shellac  
Black iron oxide  
Butyl alcohol  
Propylene glycol

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## **Sponsor Details**

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Miro Healthcare Limited  
Registered Office at Hayes Knight  
5 William Laurie Place  
Albany  
Auckland 0632

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## **Date of Preparation**

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This leaflet was prepared on 28-October-2022.