

AMBRISENTAN MYLAN

Ambrisentan film coated tablet 5 & 10 mg



What is in this leaflet

Please read this leaflet carefully before you start taking Ambrisentan Mylan.

This leaflet answers some common questions about Ambrisentan Mylan.

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 taking Ambrisentan Mylan against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. You may need to read it again.

What Ambrisentan Mylan is used for

Ambrisentan Mylan is used to treat

- Idiopathic pulmonary arterial hypertension (PAH)
- Pulmonary arterial hypertension associated with connective tissue disease (PAH-CTD)

in adult patients \geq 18 years old with WHO functional class II, III or IV symptoms.

Ambrisentan Mylan contains the active ingredient ambrisentan. It belongs to a group of medicines called endothelin receptor antagonist (ERA).

It works by widening the pulmonary arteries, making it easier for your heart to pump blood through them.

This lowers the blood pressure and relieves your symptoms.

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Ambrisentan Mylan is not recommended for use in children as there have been no studies of its effects in children.

Ambrisentan Mylan must not be used for the treatment of idiopathic pulmonary fibrosis (IPF) and must not be used in patients who have IPF with or without secondary pulmonary hypertension.

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

Before you take Ambrisentan Mylan

When you must not take it

Do not take Ambrisentan Mylan if you have an allergy to:

- any medicine containing ambrisentan.
- any of the ingredients listed at the end of this leaflet.
- any other similar medicines.

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 take Ambrisentan Mylan if:

- you have scarring of the lungs of unknown cause (a condition

known as idiopathic pulmonary fibrosis or IPF)

- you have or have had a serious liver problem
- you have raised levels of some liver enzymes (detected by blood tests).

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy or if you become pregnant soon after you stop treatment.

If it is possible you could become pregnant, use at least two reliable forms of birth control (contraception) while you are taking Ambrisentan Mylan. Talk to your doctor about this.

You must use reliable birth control (contraception) while taking Ambrisentan Mylan and for 3 months after you stop taking it.

If you are a woman who could become pregnant, your doctor will ask you to take a pregnancy test before you take Ambrisentan Mylan.

If you are a male you should avoid exposing your partner to your semen by use of appropriate contraception.

If you do become pregnant, talk to your doctor immediately.

Do not breast-feed if you are taking this medicine.

Do not give this medicine to a child under the age of 18 years. Safety and effectiveness in children younger than 18 years have not been established.

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

If it has expired or is damaged, return it to your pharmacist for disposal.

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

Before you start to take it

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

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

- liver disease
- heart disease called right heart failure
- a low number of red blood cells (anaemia)
- if you have swelling (oedema)
- low blood pressure
- kidney problems.

If any of these applies to you, your doctor will decide if Ambrisentan Mylan is suitable for you.

Blood tests

Your doctor will take blood tests to check:

- whether you have a reduced number of red blood cells (anaemia)
- that your liver is working properly.

These blood tests will be taken before you start taking Ambrisentan Mylan and throughout your treatment with Ambrisentan Mylan.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you start taking Ambrisentan Mylan.

Taking other medicines

Tell your doctor or pharmacist 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 Ambrisentan Mylan.

Some medicines may interfere with Ambrisentan Mylan. These include:

- ciclosporin A, medicine taken if you have an organ transplant. If you take ciclosporin A, do not take more than one 5 mg tablet of Ambrisentan Mylan, once a day.
- Ketoconazole, medicine used to treat fungal infection.
- Warfarin, medicine used to treat blood clot.
- Sildenafil and tadalafil, medicine used to treat erectile dysfunction.
- Rifampin, medicine used to treat tuberculosis.
- Omeprazole, medicine used to treat gastroesophageal reflux
- Digoxin, medicine used to treat certain heart diseases.
- Oral contraceptives

These medicines may be affected by Ambrisentan Mylan or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Ambrisentan Mylan

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

How much to take

The usual dose of Ambrisentan Mylan is 5 mg once daily. Your doctor may decide to increase your dose to 10 mg once daily.

If you take ciclosporin A, do not take more than one 5 mg tablet of Ambrisentan, once a day.

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

Continue taking your medicine until you finish the pack.

If you forget to take it

Take it as soon as you remember, and then go back to taking your medicine as you would normally.

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

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

While you are taking Ambrisentan Mylan

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Ambrisentan Mylan.

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

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

You must use reliable birth control (contraception) while using Ambrisentan Mylan and for 3 months after you stop taking it.

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

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked. Your doctor will need to take regular blood tests while you are taking this medicine to ensure your liver function and red blood cell (anaemia) levels remains normal.

Things you must not do

Do not take Ambrisentan Mylan to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

Things to be careful of

Be careful driving or operating machinery until you know how Ambrisentan Mylan affects you. It is not known whether Ambrisentan Mylan affects your ability to drive or use machines. However, the symptoms of your condition can make you less fit to drive.

Do not drive or operate machines if you're feeling unwell.

Be careful when drinking alcohol while you are taking this medicine.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

In case of overdose

If you take too much (overdose)

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

Symptoms of an overdose may include headache, flushing, dizziness, nausea, nasal congestion and hypotension.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Ambrisentan Mylan.

This medicine helps most people with pulmonary arterial hypertension, but it may have unwanted side effects in a few people.

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.

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

- Swelling (oedema), especially in the ankles and feet
- Headache
- Signs of anaemia, such as tiredness, weakness, shortness of breath and feeling generally unwell
- A runny or blocked nose, congestion or pain in the sinuses
- Pain in the stomach (abdomen)
- Feeling sick (nausea)
- Feeling tired, lack of energy (fatigue)
- Flushing (redness of the skin)
- Palpitations (fast or irregular heartbeats)
- Dizziness
- Shortness of breath
- Feeling weak
- Rash
- Constipation
- Vomiting
- Visual disturbance (blurred vision or changed in your ability to see clearly)

The above list includes the more common side effects of your medicine.

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

- Allergic reactions: you may notice a rash or itching or swelling (usually of the face, lips or throat) which may cause difficulty in breathing or swallowing.
- Signs that your liver may not be working as it normally should include: loss of appetite, feeling sick (nausea), being sick (vomiting), fever, unusual tiredness, pain in the stomach (abdominal pain), yellow colouring of your skin or the whites of your eyes (jaundice), your urine turns dark in colour, or itching of the skin and abnormal liver function which may show up in your blood tests.
- Anaemia that requires blood transfusion
- Heart failure (associated with swelling/oedema)
- Abnormally low blood pressure

If you notice any of these signs, tell your doctor immediately.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

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

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

After taking Ambrisentan Mylan

Storage

Keep your tablets in the bottle until it is time to take it.

If you take the tablets out of the bottle they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store Ambrisentan Mylan 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.

Product description

What it looks like

AMBRISENTAN MYLAN 5 mg is a pink, film-coated, round, biconvex tablet debossed with 'M' on one

side of the tablet and 'AN' on the other side.

AMBRISENTAN MYLAN 10 mg is a pink, film-coated, capsule shaped, biconvex tablet debossed with 'M' on one side of the tablet and 'AN1' on the other side.

Ingredients

Active ingredient(s):

Ambrisentan Mylan contains 5 & 10 mg of ambrisentan as the active ingredient.

Inactive ingredient(s):

Ambrisentan Mylan also contains:

- Microcrystalline cellulose
- Lactose
- Croscarmellose sodium
- Magnesium stearate
- Polyvinyl alcohol
- Titanium dioxide
- Macrogol 3350
- Purified talc
- Allura red AC aluminium lake C116035
- Indigo carmine aluminium lake C173015

This medicine does not contain gluten.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Ambrisentan Mylan is supplied in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland
NEW ZEALAND

Telephone: 0800 579 811

Date of Preparation

23 July 2020.
(Based on datasheet dated 16 January 2020)