Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Ambrisentan Teva 5 mg

Film-coated tablets

Each film-coated tablet contains:
ambrisentan 5 mg

Ambrisentan Teva 10 mg

Film-coated tablets

Each film-coated tablet contains:
ambrisentan 10 mg

Inactive ingredients and allergens: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'. **Read the entire leaflet carefully before you start using this medicine.** This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

Ambrisentan Teva patient safety information card
In addition to the patient leaflet, Ambrisentan Teva has a patient safety information card regarding potential harm to the fetus and potential liver injury.
This card contains important safety information that you must know before starting and during treatment with Ambrisentan Teva and you should act according to it. Read the patient safety information card and the patient leaflet before starting to use the preparation. Keep the card and the leaflet for further reading, if necessary.

Do not take Ambrisentan Teva if you are pregnant since the use of this medicine may harm the fetus (see section 2 under 'Do not use this medicine if', section 2 under 'Pregnancy, breast-feeding and fertility').

If you are a woman of child-bearing age who may become pregnant, a pregnancy test should be performed before starting treatment with Ambrisentan Teva and routinely each month while you are taking this medicine, and a month after stopping the treatment. Ensure a negative result at each pregnancy test.
You must use a reliable form of contraception while using Ambrisentan Teva and for an additional month after stopping the treatment (See section 2 under 'Pregnancy').

1. What is this medicine intended for?

Ambrisentan Teva contains the active ingredient ambrisentan.
It is used to treat pulmonary arterial hypertension (PAH) in adults. PAH is high blood pressure in the blood vessels (the pulmonary arteries) that carry blood from the heart to the lungs. In people with PAH, these arteries get narrower, so the heart has to work harder to pump blood through them. This causes people to feel tired, dizzy and short of breath.
Ambrisentan Teva widens the pulmonary arteries, making it easier for the heart to pump blood through them. This lowers the blood pressure and relieves the symptoms.
Ambrisentan Teva may also be used in combination with tadalafil that is used to treat PAH.

Therapeutic group
Endothelin receptor antagonist.

2. Before using the medicine

Do not use this medicine if:

- you are **sensitive (allergic)** to ambrisentan, soya, or any of the other ingredients of this medicine (listed in section 6).
- **you are pregnant, planning to become pregnant**, or **could become pregnant** because you are not using reliable contraception. Please read the information under 'Pregnancy'.
- you are **breast-feeding**. Read the information under 'Breast-feeding'.
- you have a **liver disease**. Talk to your physician, who will decide whether this medicine is suitable for you.
- you have **scarring of the lungs**, of unknown cause (idiopathic pulmonary fibrosis).

Special warnings regarding the use of the medicine
Talk to your physician before taking this medicine if you have:
- liver problems
- anaemia (a reduced number of red blood cells)
- swelling in the hands, ankles or feet caused by fluid *(peripheral oedema)*
- a lung disease where the veins in the lungs are blocked *(pulmonary veno-occlusive disease)*.

Your physician will decide whether Ambrisentan Teva is suitable for you.

Tests and follow-up
You will need regular blood tests
Before you start taking Ambrisentan Teva, and at regular intervals while you are taking the medicine, your physician will perform blood tests to check:
- whether you have anaemia
- whether your liver is functioning properly

It is important that you undergo these regular blood tests for as long as you are taking Ambrisentan Teva.
Signs that your liver may not be functioning properly include:
- loss of appetite
- nausea
- vomiting
- fever
- pain in your stomach (abdomen)
- yellowing of your skin or the whites of your eyes (jaundice)
- dark-coloured urine
- itching of your skin.

If you notice any of these signs: **Tell your physician immediately.**

Children and adolescents
Ambrisentan Teva is not intended for use in children and adolescents aged under 18 years as the safety and effectiveness are not known in this age group.

Drug interactions
If you are taking or have recently taken other medicines, including non-prescription medicines and food supplements, tell the physician or pharmacist.
- Your physician may need to adjust your dose of Ambrisentan Teva if you start taking cyclosporine A (a medicine used after a transplant or to treat psoriasis).
- If you are taking rifampicin (an antibiotic used to treat serious infections), your physician will monitor you when you first start taking Ambrisentan Teva.
- If you are taking other medicines used to treat PAH (e.g. iloprost, epoprostenol, sildenafil), your physician may need to monitor you.

Tell your physician or pharmacist if you are taking any of these medicines.

Pregnancy, breastfeeding and fertility
Pregnancy
Ambrisentan Teva may cause harm to fetuses of a pregnancy that began before, during or immediately after treatment with the medicine.
If you are a woman of child-bearing age, **your physician will ask you to take a pregnancy test** before you start taking Ambrisentan Teva and regularly each month while you are taking this medicine, and a month after ending the treatment. Ensure a negative result at each pregnancy test.
Do not take Ambrisentan Teva if you are pregnant or are planning to become pregnant.
You must use a reliable form of contraception while using Ambrisentan Teva and for an additional month after ending the treatment. Your physician or gynaecologist will guide you about reliable contraceptives while you are taking Ambrisentan Teva.
The physician will recommend one highly effective contraceptive to you, for example an intrauterine device or tubal sterilization or the use of a combination of methods [such as a hormonal contraceptive and a barrier contraceptive (such as a diaphragm, a contraceptive sponge or that your partner should also use a condom) or two barrier contraceptives].
If vasectomy is the chosen contraceptive method for your partner, it is mandatory to use a hormonal or barrier contraceptive in parallel.
Consult with your physician regarding the use of two contraception methods.

Tell your physician immediately if you got pregnant while you are taking Ambrisentan Teva or if you are planning to become pregnant in the near future or think you may be pregnant.

Breast-feeding
It is not known if Ambrisentan Teva is passes into breast milk.
Do not breast-feed while you are taking Ambrisentan Teva. Talk to your physician about this.

Fertility
If you are a man taking Ambrisentan Teva, it is possible that this medicine may lower your sperm count. Talk to your physician if you have any questions or concerns about this.

Driving and using machines
Ambrisentan Teva may cause side effects, such as low blood pressure, dizziness, tiredness (see section 4), that may affect your ability to drive or use machines. The symptoms of your condition can also make you less fit to drive or use machines.
Do not drive or use machines if you are feeling unwell.

Important information about some of this medicine's ingredients
Ambrisentan Teva contains lactose, lecithin (soya) and sodium
Ambrisentan Teva tablets contain small amounts of a sugar called lactose. If you have been told by your physician that you have an intolerance to some sugars, **contact your physician** before taking Ambrisentan Teva.
Ambrisentan Teva tablets contain lecithin derived from soya. If you are allergic to soya, do not use this medicine (see section 2 under 'Do not use this medicine if').
This medicine contains less than 1 mmol sodium (23 mg) in each tablet and is therefore considered sodium free.

3. How should you use the medicine?

Always use this medicine according to the physician's instructions.
You should check with the physician or the pharmacist if you are unsure about your dose or about how to take this medicine.
Only your physician will determine your dose and how you should take this medicine. The usual dose of Ambrisentan Teva is one 5 mg tablet, once a day. Your physician may decide to increase your dose to 10 mg, once a day. If you take cyclosporine A, do not take more than one 5 mg tablet of Ambrisentan Teva, once a day.
Do not exceed the recommended dose

How to take Ambrisentan Teva
It is best to take your tablet at the same time each day.
Swallow the tablet whole, with a glass of water.
Do not split, crush or chew the tablet.
You can take Ambrisentan Teva with or without food.

If you have taken more Ambrisentan Teva than you should
If you have taken too many tablets, you may be more likely to have side effects, such as headache, flushing, dizziness, nausea, or low blood pressure that could cause light-headedness. **Consult your physician or pharmacist** if you took more tablets than prescribed.
If a child has accidentally swallowed the medicine, refer immediately to a physician or to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take Ambrisentan Teva
If you forgot a dose of Ambrisentan Teva, take the tablet as soon as you remember, and take the next dose as scheduled.
Do not take two doses at the same time to make up for a forgotten dose.
Do not stop taking Ambrisentan Teva without your physician's advice.
Ambrisentan Teva is a treatment that you will need to keep on taking to control your PAH.
Adhere to the treatment as recommended by your doctor.
Do not stop taking Ambrisentan Teva unless you have agreed to this with your physician.

Do not take medicines in the dark! Check the label and dose each time you take a medicine. Wear glasses if you need them.
If you have any other questions regarding the use of the medicine, consult the physician or the pharmacist.

4. Side effects

Like all medicines, this medicine can cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

Conditions you and your physician need to look out for:
Allergic reactions
This is a common side effect that may affect **up to one in 10** people. You may notice a rash or itching and swelling (usually of the face, lips, tongue or throat), which may cause difficulty in breathing or swallowing.
Swelling (oedema), especially of the ankles and feet
This is a very common side effect that may affect **more than one in 10** people.
Heart failure
This is due to the heart not pumping out enough blood, causing shortness of breath, extreme tiredness and swelling in the ankles and legs. This is a common side effect that may affect **up to one in 10** people.
Anaemia (reduced number of red blood cells)
This is a blood disorder which can cause tiredness, weakness, shortness of breath, and generally feeling unwell. Sometimes this requires a blood transfusion. This is a very common side effect that may affect **more than one in 10** people.
Hypotension (low blood pressure)
This can cause light-headedness. This is a common side effect that may affect **up to one in 10** people.
Tell your physician straight away if you get these effects or if they happen suddenly after taking Ambrisentan Teva.
It is important to have routine blood tests, to check for anaemia and that your liver is functioning properly. **Make sure that you have also read the information in section 2** under 'You will need regular blood tests' and 'Signs that your liver may not be functioning properly'.

Other side effects
Very common side effects:
- headache
- dizziness
- palpitations (fast or irregular heart beats)
- worsening shortness of breath shortly after starting treatment with Ambrisentan Teva
- a runny or blocked nose, congestion or pain in the sinuses
- nausea
- diarrhoea
- feeling tired.

In combination with tadalafil (another PAH medicine)
In addition to the above:
- flushing (redness of the skin)
- vomiting
- chest pain/discomfort.

Common side effects:
- blurry or other changes to vision
- fainting
- abnormal blood test results for liver function
- a runny nose
- constipation
- pain in your stomach (abdomen)
- chest pain or discomfort
- flushing (redness of the skin)
- vomiting
- feeling weak
- nosebleed
- rash.

In combination with tadalafil
In addition to the above, except abnormal blood test results for liver function:
- ringing in the ears (tinnitus) only when taking the combination treatment.

Uncommon side effects:
- liver injury
- inflammation of the liver caused by the body's own defence systems (autoimmune hepatitis).

In combination with tadalafil
- sudden loss of hearing.

If a side effect has appeared, if any of the side effects get worse or when you suffer from a side effect that has not been mentioned in the leaflet, you should consult with the physician.

Reporting side effects
Side effects can be reported to the Ministry of Health "Report Side Effects of Drug Treatment" by clicking the link that is located on the Ministry of Health home page (www.health.gov.il), which refers to the on-line form for side effects reporting, or by entering the link: https://sideeffects.health.gov.il

5. How to store the medicine?

Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the sight and reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.
Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
Storage: below 25°C.

6. Additional information

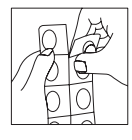
In addition to the active ingredient, the medicine also contains:
Lactose Monohydrate, microcrystalline cellulose, croscarmellose sodium, magnesium stearate, polyvinyl alcohol, titanium dioxide (E171), talc, macrogol/PEG, lecithin (soya) (E322).

What the medicine looks like and contents of the pack
Ambrisentan Teva 5 mg: white to off-white, film-coated oblong-shaped tablet, imprinted with '5' on one side - '405' on the other side.
Ambrisentan Teva 10 mg: is a white to off-white, film-coated oblong-shaped tablet, imprinted with '10' on one side - '406' on the other side.
The medicine is marketed in a bottle or blister pack that contain 30 film-coated tablets.
Not all pack sizes may be marketed.
License holder's name and address: Abic Marketing Ltd., P.O. Box 8077, Netanya.
Manufacturer's name and address: Teva Pharmaceutical Industries Ltd., P.O. Box 3190, Petach Tikva.

This leaflet was revised in August 2021 according to MOH guidelines
Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Ambrisentan Teva 5 mg: 167-41-35873
Ambrisentan Teva 10 mg: 167-42-35879

Taking out a tablet
These tablets come in special packaging to prevent children removing them.

1. **Separate one tablet:** tear along the cutting lines to separate one 'pocket' from the strip.



2. Peel back the outer layer:

3. Remove the tablet from the 'pocket'.