PULMONEXT 10 (AMBRISENTAN 10 MG FILM COATED TABLETS)

Ambrisentan (10 mg)

What is in this leaflet

1. What Pulmonext 10 is used for
2. How Pulmonext 10 works
3. Before you use Pulmonext 10
4. How to use Pulmonext 10
5. While you are using it
6. Side effects
7. Storage and Disposal of Pulmonext 10
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial number

What is Pulmonext 10 used for

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.

How Pulmonext 10 works

Pulmonext 10 contains the active substance ambrisentan. It belongs to a group of medicines called other antihypertensives (used to treat high blood pressure). Pulmonext 10 widens the pulmonary arteries, making it easier for the heart to pump blood through them. This lowers the blood pressure and relieves the symptoms.

Pulmonext 10 may also be used in combination with other medicines used to treat PAH.

Before you use Pulmonext 10

-When you must not use it

If you have severe liver disease (with or without cirrhosis, a condition where your liver has scar tissue) or levels of liver enzymes (ALT and/or ALT) which are three times the normal upper limit. Talk to your doctor, who will decide whether this medicine is suitable for you.

Do not take Pulmonext 10:

• if you are allergic to ambrisentan or any of the other ingredients of this medicine.
• if you are pregnant, if you are planning to become pregnant, or if you could become pregnant because you are not using reliable birth control (contraception)
• if you are breast feeding
• if you have scarring of the lungs, of unknown cause (idiopathic pulmonary fibrosis)

Pulmonext 10 is not recommended for children and adolescents aged under 18 years as the safety and effectiveness is not known in this age group.

-Before you start to use it

Talk to your doctor 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)
• lung disease where the veins in the lungs are blocked (pulmonary veno-occlusive disease)

Your doctor will decide whether Pulmonext 10 is suitable for you.

Pulmonext 10 tablets contain small amounts of sugar called lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Pulmonext 10.

You will need regular blood tests Before you start taking Pulmonext 10, and at regular intervals while you are taking it, your doctor will take blood tests to check:

• whether you have anaemia
• whether your liver is working properly

It is important that you have these regular blood tests for as long as you are taking Pulmonext 10.

-Taking other medications

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Your doctor may need to adjust your dose of Pulmonext 10 if you start taking:

• cyclosporine A (a medicine used after transplant or to treat psoriasis).
• rifampicin (an antibiotic used to treat serious infections) your doctor will monitor you closely when you first start taking Pulmonext 10.
• other medicines used to treat PAH (e.g. iloprost, epoprostenol, sildenafil) your doctor may need to monitor you.

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

How to use Pulmonext 10

-How much to use

Always take this medicine exactly as your doctor or pharmacist has told you to. Check with your doctor or pharmacist if you are not sure.

The usual dose of ambrisentan is one 5 mg tablet, once a day. Your doctor 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, once a day.

-When to use it

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 Pulmonext 10 with or without food.

-How long to use it

Pulmonext 10 is a treatment that you will need to keep on taking to control your PAH. Do not stop taking Pulmonext 10 unless you have agreed this with your doctor.

PULMONEXT 10 (AMBRISENTAN 10 MG FILM COATED TABLETS)

Ambrisentan (10 mg)

-If you forget to use it

If you forget to take a dose of Pulmonext 10, just take the tablet as soon as you remember, then carry on as before. Do not take two doses at the same time to make up for a forgotten dose.

-If you use too much (overdose)

If you take too many tablets you may be more likely to have side effects, such as headache, flushing, dizziness, nausea (feeling sick), or low blood pressure that could cause light-headedness. Ask your doctor or pharmacist for advice if you take more tablets than prescribed.

While you are using it

-Things you must do

Check with your doctor or pharmacist before taking your medicine and take it as prescribed by your doctor.

Pulmonext 10 may harm unborn babies conceived before, during or soon after treatment. If it is possible you could become pregnant, use a reliable form of birth control (contraception) while you are taking Pulmonext 10. Talk to your doctor about this.

If you become pregnant or think that you may be pregnant while you are taking Pulmonext 10, see your doctor immediately.

If you are a woman who could become pregnant, your doctor will ask you to take a pregnancy test before you start taking Pulmonext 10 and regularly while you are taking this medicine.

If you are a woman of child-bearing potential, do not start Pulmonext 10 treatment unless your current pregnancy test result is negative and you are practising reliable methods of contraception. Monthly pregnancy tests during Pulmonext 10 treatment is recommended.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

-Things you must not do

Do not stop taking Pulmonext 10 without your doctor's advice.

Do not take Pulmonext 10 if you are pregnant or planning to become pregnant.

It is not known if Pulmonext 10 is transferred to breast milk. Do not breast-feed while you are taking Pulmonext 10. Talk to your doctor about this.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

-Things to be careful of

If you are a man taking Pulmonext 10, it is possible that this medicine may lower your sperm count. Talk to your doctor if you have any questions or concerns about this.

Pulmonext 10 may cause side effects, such as low blood pressure, dizziness, tiredness, 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.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Conditions you and your doctor 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 doctor straight away if you get these effects or if they happen suddenly after taking Pulmonext 10.

It is important to have regular blood tests, to check for anaemia and that your liver is working properly.

Other side effects
Very common side effects:

• headache
• dizziness
• palpitations (fast or irregular heart beats)
• worsening shortness of breath shortly after starting Pulmonext 10
• a runny or blocked nose, congestion or pain in the sinuses
• feeling sick (nausea)
• diarrhoea
• feeling tired

In combination with tadalafil (another PAH medicine)
In addition to the above:

PULMONEXT 10 (AMBRISENTAN 10 MG FILM COATED TABLETS)

Ambrisentan (10 mg)

• flushing (redness of the skin)
• being sick (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)
• being sick (vomiting)
• feeling weak
• nose bleed
• 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 defences (*autoimmune hepatitis*)

In combination with tadalafil

• sudden hearing loss

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed on this leaflet.

You may report any side effects or adverse drug reaction directly to the National Centre for Adverse Drug Reaction Monitoring visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Pulmonext 10

-Storage

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the carton and blister after EXP.

The expiry date refer to the last day of that month. Store below 30°C.

-Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

-What it looks like

Pink coloured, oval shaped, biconvex, film coated tablets debossed with "A" on one side and "10" on other side.

-Ingredients

- Active ingredient(s)
  Ambrisentan 10 mg

- Inactive ingredient(s)
  Lactose monohydrate, Microcrystalline cellulose, Croscarmellose sodium, Magnesium stearate, Opadry II pink 85F540289 (film coating)

-MAL number

MALXXXXXXXAZ

Manufacturer

MSN Laboratories Pvt. Ltd.,
Formulation Division, Unit-II,
Sy. No 1277 & 1319 to 1324,
Nandigama (Village & Mandal),
Ranga Reddy District, 509228,
India

Product Registration Holder

Synercam (M) Sdn. Bhd.
A-17-7, Block A, Jaya One,
No. 72A, Jalan Professor Diraja Ungku Aziz, Seksyen 13, 46200,
Selangor

Date of revision

-17/09/2026

Serial Number

NPRA (R2) 25/244