



PACKAGE LEAFLET

MASILVA 10 mg Film Coated Tablets

Taken by mouth.

Active substance: Each film-coated tablet contains 10 mg macitentan.

Excipients: Lactose monohydrate (from cow milk), microcrystalline cellulose (PH 101) (E 460), povidone K30 (E 1201), polysorbate 80 (E 433), microcrystalline cellulose (PH 102) (E 460), croscarmellose sodium (E 468), magnesium stearate (E 572), *Opadry*® *AMB-II 88A180040 White (film coating)*: polyvinyl alcohol-partially hydrolyzed (E 1203), talc (E 553b), titanium dioxide (E 171), GMCC Type 1/glycerol fatty acids, sodium lauryl sulfate.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects that you may get. See the end of section 4 for how to report side effects.

Read all of this PACKAGE LEAFLET carefully before you start taking this medicine because it contains important information for you.

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *While you are taking this medicine, tell your doctor that you use this medicine, when you go to doctor or hospital.*
- *Exactly comply with what is written in this leaflet. Do not take this medicine in either **higher** or **lower** dose other than recommended to you.*

In this leaflet:

- 1. What MASILVA is and what it is used for***
- 2. What you need to know before you take MASILVA***
- 3. How to take MASILVA***
- 4. Possible side effects***
- 5. How to store MASILVA***

1. WHAT MASILVA IS AND WHAT IT IS USED FOR

MASILVA contains the active substance macitentan, which belongs to the class of medicines called “endothelin receptor antagonists”.

MASILVA tablets are white to off-white, biconvex and round film-coated tablets.

MASILVA is supplied in a cardboard box with 4 blisters (7 tablets in each blister), a total of 28 tablets and a package leaflet.

MASILVA is used for the long-term treatment of pulmonary arterial hypertension (PAH) in adults. PAH is high blood pressure in the blood vessels that carry blood from the heart to the lungs (the pulmonary arteries). 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.

MASILVA widens the pulmonary arteries, making it easier for the heart to pump blood through them. This lowers the blood pressure, relieves the symptoms and improves the course of the disease.



2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE MASILVA

DO NOT TAKE MASILVA in the following conditions:

- If you are allergic to macitentan or any of the other ingredients of this medicine (see the list of “Excipients”).
- 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). See section ‘Pregnancy’.
- If you are breastfeeding. See section ‘Breastfeeding’.
- If you have liver disease or if you have very high levels of liver enzymes in your blood. Talk to your doctor, who will decide whether this medicine is suitable for you.

If any of these apply to you, please tell your doctor.

USE MASILVA CAREFULLY in the following conditions:

Talk to your doctor or pharmacist before taking this medicine:

- If you have anemia (a reduced number of red blood cells)
- If you have kidney failure

You will need blood tests, as indicated by your doctor:

Your doctor will take blood test before you start MASILVA treatment and during treatment to test:

- Whether you have anemia (a reduced number of red blood cells)
- Whether your liver is working properly

If you have anemia (a reduced number of red blood cells), you may have the following signs:

- Dizziness
- Fatigue/malaise/weakness
- Fast heart rate, palpitations
- Pallor

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

Signs that your liver may not be working properly include:

- Feeling sick (nausea)
- Vomiting
- Fever
- Pain in your stomach (abdomen)
- Jaundice (yellowing of your skin or the whites of your eyes)
- Dark-colored urine
- Itching of your skin
- Unusual tiredness or exhaustion (lethargy or fatigue)
- Flu-like syndrome (joint and muscle pain with fever)

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

If you have kidney problems, talk to your doctor before using MASILVA. Macitentan may lead to more reduction of blood pressure and decrease in hemoglobin (a protein inside red blood cells) in patients with kidney problems.

In patients with pulmonary veno-occlusive disease (obstruction of the lung veins), the use of medicines for treatment of PAH, including MASILVA, may lead to pulmonary edema (edema in the lungs). If you have signs of pulmonary edema when using MASILVA, such as a sudden, important



increase in breathlessness and low oxygen, **tell your doctor immediately**. Your doctor may perform additional tests, and will determine what treatment regimen is most suitable for you.

If any of these warnings apply to you, even at any time in the past, please consult your doctor.

Taking MASILVA with food and drink

MASILVA can be taken with or without food.

Pregnancy

Consult your doctor or pharmacist before taking this medicine.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

MASILVA 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 MASILVA. Talk to your doctor about this.

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

If you become pregnant or think that you may be pregnant while you are taking MASILVA, or shortly after stopping MASILVA (up to 1 month), 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 MASILVA and regularly (once a month) while you are taking MASILVA.

If you realize that you are pregnant during the treatment, consult your doctor or pharmacist immediately.

Breastfeeding

Consult your doctor or pharmacist before taking this medicine.

It is not known if MASILVA passes into breast milk. Do not breastfeed while using MASILVA.

Fertility

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

Driving and using machines

MASILVA can cause side effects like headache (listed in section 4), and the symptoms of your condition can also make you less fit to drive.

Important information about some of the ingredients of MASILVA

MASILVA contains a sugar called lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Other medicines and MASILVA

MASILVA can affect other medicines.

If you take MASILVA together with other medicines including those listed below, the effects of MASILVA or the other medicines might be altered. Please talk to your doctor or pharmacist if you are taking any of the following medicines:

- Rifampicin, clarithromycin, telithromycin, ciprofloxacin, erythromycin (antibiotics used to treat infections)
- Phenytoin (a medicine used to treat seizures)



- Carbamazepine (used to treat depression and epilepsy)
- St. John's Wort (an herbal preparation used to treat depression)
- Ritonavir, saquinavir (used to treat HIV infections)
- Nefazodone (used to treat depression)
- Ketoconazole (except shampoo), fluconazole, itraconazole, miconazole, voriconazole (medicines used against fungal infections)
- Amiodarone (to control the heartbeat)
- Cyclosporine (used to prevent organ rejection after transplant)
- Diltiazem, verapamil (to treat high blood pressure or specific heart problems)

MASILVA with food

If you are using piperine as a dietary supplement, this may alter how the body responds to some medicines, including MASILVA. Please talk to your doctor or pharmacist, should this be the case.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

3. HOW TO TAKE MASILVA

Instructions for proper use and dose/frequency of administration

MASILVA should only be prescribed by a doctor experienced in the treatment of pulmonary arterial hypertension. Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. The recommended dose of MASILVA is one 10 mg tablet, once a day.

Route and method of administration

Swallow the tablet whole, with a glass of water. Do not chew or break the tablet. You can take MASILVA with or without food. It is best to take the tablet at the same time each day.

Different age groups

Use in children

MASILVA should not be used in children under 18 years of age.

Use in elderly

No dosage adjustment is required in patients over 65 years of age.

Special conditions

Kidney failure

If you have kidney problems, your doctor will decide whether it is appropriate for you to use MASILVA. Macitentan may lead to more reduction of blood pressure and decrease in the levels of hemoglobin (a protein in the blood) in patients with kidney problems.

Liver failure

If you have liver disease or if you have very high levels of liver enzymes in your blood, your doctor will decide whether this medicine is suitable for you. MASILVA should not be started if you have severe liver failure.

If you think that the effect of MASILVA is too strong or too weak, talk to your doctor or pharmacist.

If you use more MASILVA than you should

If you use more MASILVA than you should, talk to a doctor or pharmacist.

If you have taken more tablets than you have been told to take, you may experience headache, nausea, or vomiting.



If you forget to use MASILVA

Do not take a double dose to make up for a forgotten dose.

If you forget to take MASILVA, take a dose as soon as you remember, then continue to take your tablets at the usual times. Do not take a double dose to make up for a forgotten tablet.

If you stop using MASILVA

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

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, side effects may occur in patients with sensitivity to the ingredients of MASILVA.

If you notice any of the following, stop using MASILVA and IMMEDIATELY inform your doctor or go to the nearest hospital emergency department:

- Hypersensitivity reactions, angioedema (swelling around the eyes, and of the face, lips, tongue and throat), itching and/or rash.

These are all very serious side effects. If you have any of these, it means that you are severely allergic to MASILVA. You may require urgent medical attention or hospitalization.

Side effects are classified in the following frequencies:

- Very common : may occur in at least 1 in 10 patients.
- Common : may occur in less than 1 in 10 but more than 1 in 100 patients.
- Uncommon : may occur in less than 1 in 100 but more than 1 in 1000 patients.
- Rare : may occur in less than 1 in 1,000 but more than 1 in 10,000 patients.
- Very rare : may occur in less than 1 in 10,000 patients.
- Not known : cannot be estimated from the available data.

Very common

- Anemia (low number of red blood cells) or reduced hemoglobin (a protein inside red blood cells)
- Headache
- Bronchitis (inflammation of the airways)
- Nasopharyngitis (inflammation of the throat and nasal passages)
- Edema (swelling), especially of the ankles and feet

Common

- Pharyngitis (inflammation of the throat)
- Influenza (flu)
- Urinary tract infection (bladder infection)
- Hypotension (low blood pressure)
- Nasal congestion (blocked nose)
- Leukopenia (decreased white blood cell counts)
- Thrombocytopenia (decreased blood platelet counts)
- Aminotransferase elevation (increased liver enzymes)



Uncommon

- Allergic reactions (swelling around the eyes, face, lips, tongue or throat, itching and/or rash).

If you get any side effects not listed in this leaflet, inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects including any possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. You can also report side effects directly via the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE MASILVA

Keep MASILVA out of reach and sight of children and in its original package.

Store at room temperature below 30°C and in its own pack.

Use this medicine in accordance with the expiry date.

Do not use MASILVA after the expiry date which is stated on the package.

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.

Marketing Authorization Holder:

DEVA Holding A.Ş.

Küçükçekmece – İSTANBUL / TÜRKİYE

Manufacturing site:

DEVA Holding A.Ş.

Kapaklı – TEKİRDAĞ / TÜRKİYE

This package leaflet was approved on 08/05/2023.