

Silkay 125 mg Tablet

Bosentan monohydrate eq. to Bosentan (125 mg)

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What Silkay 125 is used for

Silkay 125 is a prescription medicine used to treat people with certain types of pulmonary arterial hypertension (PAH), which is high blood pressure in the vessels of the lungs.

How Silkay 125 works

Silkay 125 tablets contain Bosentan, which belongs to the class of medicines called “endothelin receptor antagonists”.

Bosentan blocks a naturally occurring hormone called endothelin-1 (ET-1), which causes blood vessels to narrow. Thus, it acts to reduce abnormally high blood pressure by widening these blood vessels.

Before you use Silkay 125

- When you must not use it

Do not take Silkay 125:

- if you are allergic to bosentan or any of the other ingredients of this medicine
- if you have liver problems (ask your doctor)
- if you are pregnant, or could get pregnant because you are not using reliable contraceptive methods. Please read the information under “Contraceptives” and “Taking other medicines”
- if you are taking cyclosporine A (a medicine used after a transplant)

Pregnancy and Lactation

Do NOT take Silkay 125 if you are pregnant or planning to become pregnant.

Pregnancy tests

Silkay 125 may harm unborn babies conceived before starting or during

treatment. If you are a woman who could become pregnant, your doctor will ask you to take a pregnancy test before you start taking Silkay 125, and regularly while you are taking it.

Contraceptives

If it is possible that you could become pregnant, use a reliable form of birth control (contraception) while you are taking Silkay 125. Your doctor or gynecologist will advise you about reliable contraceptive methods while taking Silkay 125.

Because Silkay 125 may make hormonal contraception (e.g. oral, injection, implant, or skin patches) ineffective, this method on its own is not reliable. Therefore, if you use hormonal contraceptives you must also use a barrier method (e.g. female condom, diaphragm, contraceptive sponge, or your partner must also use a condom). Monthly pregnancy tests are recommended while you are taking Silkay 125 and are of child-bearing age.

Tell your doctor immediately if you become pregnant while you are taking Silkay 125, or plan to become pregnant in the near future.

Breastfeeding

Tell your doctor immediately if you are breastfeeding. You are advised to stop breastfeeding if Silkay 125 is prescribed for you, because it is not known whether this medicine passes into breast milk.

Fertility

If you are a man taking Silkay 125, it is possible that this medicine may lower your sperm count.

- Before you start to use it

Tests your doctor will do before treatment

- a blood test to check your liver function
- a blood test to check for anemia (low hemoglobin)
- a pregnancy test if you are a woman of childbearing potential

Some patients taking Silkay 125 have been found to have abnormal liver function tests and anemia (low hemoglobin).

Tests your doctor will do during treatment

During treatment with Silkay 125, your doctor will arrange for regular blood tests to check for changes in your liver function and hemoglobin level.

Blood tests for liver function

These will be done every month for the duration of treatment with Silkay 125.

Blood tests for anemia

These will be done every month for the first 4 month of treatment, then every 3 months after that, as patients taking Silkay 125 may get anemia.

- Taking other medicines

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

- cyclosporine A (a medicine used after a transplant)
- tacrolimus, sirolimus (used to prevent organ transplantation rejection)
- glibenclamide (a diabetes medicine)
- nevirapine (used to treat HIV)
- ketoconazole, itraconazole, fluconazole and voriconazole (anti-fungal medicines)
- hormonal contraceptives (oral, injectable, and implantable)
- simvastatin (used to lower cholesterol levels)
- rifampicin (used to treat infection)
- warfarin (used to thin the blood)
- sildenafil and tadalafil (used to treat erectile dysfunction)
- digoxin (used to treat heart failure and to treat certain types of irregular heartbeats)
- lopinavir/ritonavir (treatment of HIV or AIDS)

How to use Silkay 125

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

- How much to use

Always take this medicine exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

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Adults

For the first 4 weeks, you will take a 62.5mg tablet twice daily. Depending on how you respond to the medicine, your doctor may increase the dosage after four weeks to a 125mg tablet twice daily.

Children and adolescents

Based on the age and condition of your child, your doctor will decide the suitability of this medicine and its dose. lopo

If you have the impression that the effect of Silkay 125 is too strong or too weak, talk to your doctor in order to find out whether your dose needs to be changed.

Safety and efficacy in pediatric patients have not been established.

- When to use it

Tablets should be taken morning and evening, with or without food.

- How long to use it

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

- If you forget to use it

If you forget to take Silkay 125, 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 forgotten dose.

- If you use too much (overdose)

If you take more tablets than you have been told to take, contact your doctor immediately.

The symptoms of overdose include of nausea, vomiting, low blood pressure, dizziness, sweating and blurred vision.

While you are using it

- Things you must do

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Things you must not do

Do not stop taking Silkay 125 or alter the dose, without first checking with your doctor.

- Things to be careful of

Driving and using machines

Silkay 125 has no or negligible influence on the ability to drive and use machines. However, Silkay 125 can induce hypotension (decrease of your blood pressure) which can make you feel dizzy, affect your vision and affect your ability to drive and use machines. Therefore, if you feel dizzy or that your vision is blurred while taking Silkay 125, do not drive or operate any tools or machines.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects:

- Abnormal liver function
- Anemia (low haemoglobin) and may require blood transfusion

Common side effects:

- Anemia
- Hypersensitivity reaction (including skin inflammation, itching and rash)
- Fainting (syncope)
- Fast or irregular heartbeat (palpitation)
- Low blood pressure
- Stuffy nose
- The return of stomach acid or contents back up into the esophagus
- Diarrhea
- Redness of face and skin

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

Storage and Disposal of Silkay 125

-Storage

Keep medicines out of reach of children. Store at temperature of not more than 30°C.

-Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will you protect the environment.

Product Description

- What it looks like?

Orange-white, oval, biconvex, film coated tablet with engraved 125 on one side and plain on the other side.

- Ingredients

- Active ingredient:

Bosentan monohydrate eq. to Bosentan

- Inactive ingredients:

Microcrystalline cellulose (Avicel PH 101), Crospovidone (Crospovidone XL-10), Povidone (PVP K-30), Sodium lauryl sulfate, Purified water, Sodium starch glycolate, Glyceryl behenate, Colloidal silicon dioxide (Aerosil 200), Magnesium stearate, Hypromellose (HPMC 2910), Polyethylene glycol (PEG 400), Isopropyl alcohol, Kollicoat IR [Combination of Polyvinyl alcohol units (75%); Polyethylene glycol units (25%); Colloidal anhydrous silica (Approx. 0.3%)], Titanium dioxide, Talc, Iron oxide red (C.I. No. 77491), Iron oxide yellow (C.I. No. 77492), Polyethylene glycol (PEG 6000) and Copovidone

- MAL Number: -

MAL21016011AZ

Manufacturer

UNISON LABORATORIES CO., LTD.
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Product Registration Holder

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