

PROART Tablets 62.5 mg and PROART Tablets 125 mg

(Bosentan Monohydrate Tablets 62.5 mg and 125 mg)

Consumer Medication Information Leaflet (RiMUP)

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This leaflet answers some common questions about **PROART Tablets**.

It does not contain all of 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 **PROART Tablets** against the benefits it is expected to 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 PROART Tablets are used for

PROART Tablets contain the active ingredient bosentan. It is used for the treatment of high blood pressure in the blood vessels between the heart and the lungs. This condition is called pulmonary arterial hypertension.

How PROART Tablets work

PROART 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.

Your doctor however, may have prescribed this medicine for another purpose.

Ask your doctor if you have any questions why it has been prescribed for you.

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

Before you use PROART Tablets

When you must not use it

Do not take PROART Tablets:

- If you are allergic to bosentan or any of the other ingredients of this medicine (see product description at the end of this leaflet). An allergic reaction may include skin rash, itching, swelling of the face, lips, tongue and throat or difficulty in breathing.
- If you have moderate or severe 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 or to treat psoriasis)

Do not use this medicine after the expiry date printed on the pack has expired 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 **PROART Tablets**, talk to your doctor or pharmacist.

Before you start to use it

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

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

- anaemia (low haemoglobin)
- low blood pressure (Hypotension)
- liver or kidney disease

- heart failure
- HIV infection

Tests your doctor will do before treatment

- a blood test to check your liver function
- a blood test to check for anaemia (low haemoglobin)
- a pregnancy test if you are a woman of child-bearing potential

Some patients taking bosentan have been found to have abnormal liver function tests and anaemia (low haemoglobin).

Tests your doctor will do during treatment

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

Blood tests for liver function

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

Blood tests for anaemia

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

Pregnancy and Lactation

DO NOT take bosentan if you are pregnant or planning to become pregnant.

Pregnancy tests

Bosentan 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 bosentan, and regularly while you are taking bosentan.

Contraceptives

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

Because bosentan 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 bosentan and are of child-bearing age.

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

Lactation

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

If you have not told your doctor about any of the above, tell them before you start taking **PROART Tablets**.

If you are not sure, talk to your doctor or pharmacist before taking **PROART Tablets**.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and PROART Tablets may interact with each other.

- cyclosporine A (a medicine used after a transplant or to treat psoriasis)
- tacrolimus, sirolimus (medicines to prevent organ transplantation rejection)
- glibenclamide (a diabetes medicine)
- nevirapine, lopinavir/ritonavir, other ritonavir-boosted protease inhibitors (medicines used to treat HIV),
- ketoconazole, itraconazole, fluconazole and voriconazole (anti-fungal medicines)
- hormonal contraceptives (oral, injectable, transdermal and implantable)

- simvastatin, (medicines used to lower cholesterol levels)
- rifampicin (used to treat tuberculosis and other infections)
- warfarin (used to thin the blood).
- sildenafil and tadalafil (medicine used to treat erectile dysfunction)
- digoxin (used to treat heart failure and to treat certain types of irregular heartbeats)

If you have not told your doctor about any of these, tell them before you take **PROART Tablets**.

These medicines may be affected by bosentan or may affect how well it works. You may need to use different amounts of your medicines, or take different medicines. Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking bosentan.

How to use PROART Tablets

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 this leaflet, ask your doctor or pharmacist for help.

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.

The usual dose is one tablet, twice daily. For the first 4 weeks you will take a 62.5 mg tablet twice daily.

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

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

Children and adolescents

Based on the age and condition of your child, your doctor will decide the

suitability of this medicine and its dose.

How to take it

PROART Tablets can be taken with or without food. Swallow PROART Tablets with a glass of water.

When to use it

Take **PROART Tablets** exactly as your doctor tells you to take it.

Take **PROART Tablets** daily in the morning and in the evening.

How long to use it

Do not stop taking **PROART Tablets** unless your doctor tells you to.

Stopping your treatment may lead to a worsening of your symptoms. Your doctor may tell you to reduce the dose over a few days before stopping completely.

If you forget to use it

Do not miss a dose of **PROART Tablets**. If you miss a dose, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the dose you missed and take the next dose of **PROART Tablets** at your regular time.

If you are not sure what to do, ask your doctor or pharmacist. Do not take a double dose to make up for the dose that you missed. This may increase the chance of getting an unwanted side effect.

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

If you use too much (overdose)

Immediately telephone your doctor for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much of PROART Tablets. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take this leaflet or some tablets with you so your doctor will know what you have taken.

The symptoms of overdose include headache, felling sick, vomiting, dizziness, sweating, blurred vision, low blood pressure and increase in heart rate.

While you are using PROART Tablets

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking **PROART Tablets**.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking **PROART Tablets**.

It is very important that you have a liver function blood test before you start treatment and every month after that.

PROART Tablets can cause liver damage if it is not found early. Because this side effect may not cause symptoms at first, only a blood test can show that you have early liver damage. Regular blood tests let your doctor change or stop your therapy before there is permanent damage.

You should have a blood test for anemia every month for the first 4 months of treatment, and then every 3 months after that, as patients taking bosentan may get anaemia. You need to have pregnancy tests monthly if you are a female of childbearing age.

DO NOT take bosentan if you are pregnant or planning to become pregnant.

Visit your doctor regularly so they can check on your progress.

Things you must not do

Do not stop taking **PROART Tablets** or alter the dose, without first checking with your doctor.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use **PROART Tablets** to treat any other complaints unless your doctor says to.

Things to be careful of

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

Side effects

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

Like all medicines, **PROART Tablets** can have side effects, although not everybody gets them.

Do not be alarmed by the following list of side effects. You may not experience any of them

Very serious side effects

If any of the following happens, stop taking PROART Tablets and tell your doctor immediately or go to the casualty/ emergency department at your nearest hospital immediately.

- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- chronic liver disease, liver failure

Signs that your liver may not be working properly include

- nausea (urge to vomit)
- vomiting
- fever (high temperature)
- pain in your stomach (abdomen) or discomfort
- jaundice (yellowing of your skin or the whites of your eyes)
- dark-coloured urine
- itching of your skin
- lethargy or fatigue (unusual tiredness or exhaustion)
- flu-like syndrome (joint and muscle pain with fever)

These are very serious side effects. If you have them you may need urgent medical attention or hospitalisation.

Serious side effects

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- fast heart beat, chest pain
- fainting
- low blood pressure
- bleeding or bruising more easily than normal, frequent infections such as fever, severe chills, sore throat or mouth ulcers, tiredness, headaches, being short of breath when exercising, dizziness and looking pale
- ankle and leg swelling

The above list includes serious side effects that may require medical attention.

Other side effects

Tell your doctor if you notice any of the following:

- headache
- blurred vision
- heart burn, diarrhoea
- redness of your skin, rash
- feeling of tension or fullness in the nose, cheeks and behind your eyes
- flushing

If you notice any of these signs tell your doctor immediately

Laboratory Abnormalities

- liver function test abnormal
- decreased blood cell counts

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

Ask your doctor or pharmacist to answer any questions you may have.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835549, or visiting the website npra.moh.gov.my [Public→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]"

Storage and Disposal of PROART Tablets

Storage: Store below 30°C

Disposal: Return any unused or expired medicine to your doctor, pharmacist or health care professional for safe disposal

Product Description

What it looks like

For Proart tablets 62.5 mg:

Light peach to peach colored film coated round shaped biconvex tablet debossed with '62.5' on one side and plain on other side.

For Proart tablets 125 mg:

Light peach to peach colored film coated oval shaped biconvex tablet debossed with '125' on one side and plain on other side.

Ingredients

Active ingredients:

Bosentan Monohydrate

Inactive ingredients:

Maize starch, Pregelatinized starch, Sodium starch glycolate, Povidone, Purified water, Glycerol dibehenate Magnesium stearate, Opadry 21K520019 (Yellow)

MAL Number:

Product Registration Holder

*RANBAXY (MALAYSIA) SDN. BHD.
a SUN PHARMA company
Lot 23, Bakar Arang Industrial Estate,
08000 Sungai Petani, Kedah,
Malaysia.*

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