What is in this leaflet

This leaflet answers some common questions about BOSENTAN MYLAN.

It does not contain all 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 BOSENTAN MYLAN against the benefits they expect it will 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 BOSENTAN MYLAN is taken for

BOSENTAN MYLAN 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.

BOSENTAN MYLAN contains the active ingredient bosentan. It belongs to a class of medicines called endothelin receptor antagonists.

This medicine acts to reduce abnormally high blood pressure by widening the blood vessels between the heart and the lungs.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

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

Before you take BOSENTAN MYLAN

When you must not take it

Do not take BOSENTAN MYLAN if you have an allergy to:

- any medicine containing bosentan
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take this medicine if you are pregnant or intend to become pregnant or you intend to father a child. You must stop taking this medicine at least 3 months before trying to become pregnant.

BOSENTAN MYLAN may cause harm to the developing baby if you take it during pregnancy and the three months before becoming pregnant. You and your partner should take adequate contraceptive precautions while taking BOSENTAN MYLAN.

Do not breast-feed if you are taking this medicine.

Tell your doctor immediately if you are breastfeeding. You are advised to stop breastfeeding if this medicine is prescribed for you because it is not known if this medicine passes into the milk in women who are breastfeeding.

Do not take BOSENTAN MYLAN if you have moderate to severe liver disorder.

- are being treated with cyclosporine A (a medicine used after a transplant or to treat psoriasis)
- are being treated with glibenclamide (a medicine used for diabetes).

Do not take this medicine after the expiry date printed on the pack 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 this medicine, talk to your doctor.

Before you start to take it

BOSENTAN MYLAN may harm sperm. All men should use effective birth control while taking this medicine and for 3 months after they stop taking it.

If sexually active, you must use a hormonal and barrier method of contraception.

Tell your doctor if:

- you are a woman of childbearing potential and not using reliable contraceptive methods. You must have a negative pregnancy test before beginning treatment. The test should be performed on the second day of a normal menstrual period or 11 days after the last unprotected sexual intercourse, whichever is later. Your doctor will advise you about using reliable contraception before taking or whilst taking this medicine. This medicine may reduce the effectiveness of hormone contraceptives such as the pill and hormone patches, implants or injections.
It is important to use other contraceptives, like condoms or intrauterine device. You should have a pregnancy test every month while taking this medicine. You must stop taking this medicine for at least 3 months prior to becoming pregnant.

- You are breastfeeding or intending to breastfeed. It is not known whether BOSENTAN MYLAN passes into breast milk.
- you have allergies to any other medicines, foods, preservatives or dyes
- you have or have had any of the following medical conditions:
  - heart disease
  - anaemia
  - hypotension (low blood pressure)
  - liver or kidney disorders
  - heart failure
  - HIV infection.

If you have not told your doctor about any of the above, tell them before you start taking BOSENTAN MYLAN.

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 BOSENTAN MYLAN may interfere with each other. These include:

- hormonal contraceptives (oral, injectable, transdermal and implantable)
- simvastatin, medicines for lowering blood fats
- medicines used to treat diabetes such as glibenclamide
- medicines used to treat fungal infections such as ketoconazole, fluconazole and voriconazole
- medicines to prevent organ transplantation rejection such as cyclosporine A, tacrolimus and sirolimus
- medicines for rheumatoid arthritis or psoriasis/dermatitis
- lopinavir+ritonavir or other ritonavir-boosted protease inhibitors (used to treat HIV infection)
- rifampicin a medicine used to treat bacterial infections e.g. tuberculosis
- anticonvulsant medicines (used to treat seizures) such as carbamazepine, phenobarbital and phenytoin
digoxin a medicine used to treat heart rhythm disorders
- St John’s wort, a herbal preparation sometimes used to treat depression
- Sildenafil and tadalafil, medicines used to treat erectile dysfunction and pulmonary hypertension.

These medicines may be affected by BOSENTAN MYLAN or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take BOSENTAN MYLAN

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 the box, ask your doctor or pharmacist for help.

How much to take

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 4 weeks to a 125 mg tablet twice daily.

How to take it

BOSENTAN MYLAN is taken orally, in the morning and evening.

Swallow the tablets whole with a full glass of water.

When to take it

Take your medicine at about the same time(s) each day. Taking it at the same time(s) each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

How long to take it

Continue taking your medicine for as long as your doctor tells you. This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, if there is still a long period before your next dose take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

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

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) 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 BOSENTAN MYLAN. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.
Symptoms of an overdose may include severe headache, nausea and vomiting, dizziness, sweating and blurred vision.

While you are taking **BOSENTAN MYLAN**

**Things you must do**

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking **BOSENTAN MYLAN**.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking **BOSENTAN MYLAN**. It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Keep all of your doctor’s appointments so that your progress can be checked. Your doctor may do some tests, from time to time to make sure the medicine is working and to prevent unwanted side effects.

It is very important that you have a liver function blood test before you start treatment and every month after that. **BOSENTAN MYLAN** 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 anaemia after 1 and 3 months, and then every 3 months for the rest of your treatment.

You need to have pregnancy tests monthly if you are a female of childbearing age.

**Things you must not do**

Do not take **BOSENTAN MYLAN** to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor. If you stop taking it suddenly, your condition may worsen.

**Things to be careful of**

Be careful driving or operating machinery until you know how **BOSENTAN MYLAN** affects you. If you feel dizzy while taking this medicine do not drive, operate machinery or do anything else that could be dangerous.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

**Side effects**

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking **BOSENTAN MYLAN**. This medicine helps most people with pulmonary arterial hypertension but it may have unwanted side effects in a few people. All medicines can have side effects.

It is very important that you have a liver function blood test before you start treatment and every month after that. **BOSENTAN MYLAN** 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 anaemia after 1 and 3 months, and then every 3 months for the rest of your treatment.

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

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- headache
- inflamed throat and irritated nasal passages
- hot flushes
- ankle and leg swelling
- fast heart beat
- tiredness
- itching, rash, redness of the skin
- blurred vision
- dizziness
- diarrhoea

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- wheezing, swelling of the face, lips, mouth or throat, shortness of breath or difficulty in breathing (severe allergic reaction)
- bruising or bleeding more easily
- nausea
- vomiting
- fever
- unusual tiredness
- yellowing of the skin or the whites of your eyes
- chest pain

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

Tell your doctor or pharmacist if you notice anything that is making you feel unwell. Other side effects not listed above may also occur in some people.

Some of these side effects (for example, changes in liver function) can only be found when your doctor does tests from time to time to check your progress.
Storage

Keep your tablets in the pack until it is time to take them. If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store BOSENTAN MYLAN or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.
A locked cupboard at least one-and-a half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

BOSENTAN MYLAN 62.5 mg, are white to off-white, film-coated, round tablets marked with “M” on one side of the tablet and “BN1” on the other side.

BOSENTAN MYLAN 125 mg, are white to off-white, film-coated, oval, tablets marked with “M” on one side of the tablet and “BN2” on the other side.

Both strengths of BOSENTAN MYLAN come in blister packs of 56 tablets, or bottle packs of 60 tablets.

Ingredients

Each BOSENTAN MYLAN tablet contains 62.5 mg or 125 mg of the active ingredient bosentan (as monohydrate).

Each tablet also contains:

- maize starch
- pregelatinised maize starch
- sodium starch glycollate
- povidone
- sodium lauryl sulfate
- glyceryl behenate
- magnesium stearate
- opadry white 03K580000
- surelease clear E-7-19040.

This medicine does not contain lactose, sucrose, gluten or tartrazine.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: (09) 579 2792

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