Package leaflet: information for the user

Bisoprolol Syri Pharma 0,5 mg/ml, drank
Bisoprolol fumarate

Read all of this 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Bisoprolol Syri Pharma 0,5 mg/ml, drank but it will be referred to as Bisoprolol throughout this leaflet.

What is in this leaflet

1. What Bisoprolol is and what it is used for

The active substance in this medicinal product is Bisoprolol fumarate. Bisoprolol belongs to a group of medicines called beta-blockers. Beta-blockers protect the heart against too much activity. Bisoprolol is used in combination with other medicines to treat stable heart failure.

Heart failure occurs when the heart muscle is too weak to pump blood around the circulation adequately. This results in breathlessness and swelling.

Bisoprolol slows down the heart rate and makes the heart more efficient at pumping blood around the body.

Bisoprolol is also used to treat high blood pressure (hypertension) and angina pectoris (chest pain caused by blockages in the arteries that supply the heart muscle).

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Bisoprolol

Do not take Bisoprolol

Do not take Bisoprolol if one of the following conditions applies to you:
- if you are allergic(hypersensitivity) to Bisoprolol or to any of the other ingredients of this medicine (listed in section 6).
- severe asthma
- severe blood circulation problems in your limbs (such as Raynaud's syndrome), which

may cause your fingers and toes to tingle or turn pale or blue
- untreated phaeochromocytoma, which is a rare tumour of the adrenal gland
- metabolic acidosis, which is a condition when there is too much acid in the blood.

Do not take Bisoprolol if you have one of the following heart problems:
- acute heart failure
- worsening heart failure requiring injection of medicines into a vein, that increase the force of contraction of the heart
- slow heart rate
- low blood pressure
- certain heart conditions causing a very slow heart rate or irregular heartbeat
- cardiogenic shock, which is an acute serious heart condition causing low blood pressure and circulatory failure.

Warnings and precautions
Talk to your doctor or pharmacist before taking Bisoprolol.
If you have any of the following conditions; he or she may want to take special care (for example give additional treatment or perform more frequent checks):
- diabetes. Bisoprolol can hide the symptoms of low blood sugar
- strict fasting
- any certain heart diseases such as disturbances in heart rhythm, or severe chest pain at rest (Prinzmetal's angina)
- kidney or liver problems
- have any problems with the circulation in your limbs, are taking verapamil or diltiazem, medicines used to treat heart conditions. Concomitant use is not recommended, see also "Other medicines and Bisoprolol "
- chronic lung disease or less severe asthma
- have (or have had) psoriasis (a recurring skin rash)
- have phaeochromocytoma (a rare tumour of the adrenal gland). Your doctor will need to treat this before prescribing Bisoprolol for you
- thyroid disorder. Bisoprolol can hide symptoms of an overactive thyroid.

In addition, tell your doctor if you are going to have:
- desensitization therapy (for example for the prevention of hay fever), because Bisoprolol may make it more likely that you experience an allergic reaction, or such reaction may be more severe
- are going to be given a general anaesthetic during an operation – tell your doctor that you are taking Bisoprolol
- worsening of symptoms of blockage of the main blood vessels to the legs, especially at the start of treatment.

If you have chronic lung disease or less severe asthma please inform your doctor immediately if you start to experience new difficulties in breathing, cough, wheezing after exercise, etc. when using Bisoprolol.

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

<u>Do not take the following medicines with Bisoprolol without special advice from your doctor:</u>
- certain medicines used to treat irregular or abnormal heartbeat (Class I antiarrhythmic

medicines such as quinidine, disopyramide, lidocaine, phenytoin; flecainide, propafenone)
- certain medicines used to treat high blood pressure, angina pectoris or irregular heartbeat (calcium antagonists such as verapamil and diltiazem)
- medicines for controlling the blood pressure or medicines for heart problems (such as amiodarone, amlodipine, clonidine, digitalis glycosides, diltiazem, disopyramide, felodipine, flecainide, lidocaine, methyldopa, moxonidine, nifedipine, phenytoin, propafenone, quinidine, rilmenidine, verapamil). However, **do not stop taking these medicines** without checking with your doctor first.

Check with your doctor before taking the following medicines with Bisoprolol; your doctor may need to check your condition more frequently:
- certain medicines used to treat high blood pressure or angina pectoris (dihydropyridine-type calcium antagonists such as felodipine and amlodipine)
- certain medicines used to treat irregular or abnormal heartbeat (Class III antiarrhythmic medicines such as amiodarone)
- beta-blockers applied locally (such as timolol eye drops for glaucoma treatment)
- certain medicines used to treat for example Alzheimer's disease or glaucoma (parasympathomimetics such as tacrine or carbachol) or medicines that are used to treat acute heart problems (sympathomimetics such as isoprenaline and dobutamine)
- antidiabetic medicines including insulin
- anaesthetic agents (for example during surgery)
- digitalis, used to treat heart failure
- non-steroidal anti-inflammatory medicines (NSAIDs) used to treat arthritis, pain or inflammation (for example ibuprofen or diclofenac)
- any medicine, which can lower blood pressure as a desired or undesired effect such as antihypertensives, certain medicines for depression (tricyclic antidepressants such as imipramine or amitriptyline), certain medicines used to treat epilepsy or during anaesthesia (barbiturates such as phenobarbital), or certain medicines to treat mental illness characterized by a loss of contact with reality (phenothiazines such as levomepromazine)
- mefloquine, used for prevention or treatment of malaria
- depression treatment medicines called monoamine oxidase inhibitors (except MAO-B inhibitors) such as moclobemide.
- medicines used for a blocked nose

Pregnancy and breast-feeding

Pregnancy

Bisoprolol can be harmful to the pregnancy and/or to the child (increased possibility of premature birth, miscarriage, retarded growth, low blood glucose level and reduced heart rate of the child). Therefore do not use this medicine during pregnancy.

Breast-feeding

It is not known whether Bisoprolol passes into human breast milk. Therefore, breastfeeding is not recommended during therapy with Bisoprolol.

No information is available on the effects of Bisoprolol on fertility.

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

Driving and using machines
The use of Bisoprolol may sometimes result in dizziness or fatigue (see 'Possible side effects'). If you suffer from these side effects, do not operate vehicles and/or machines. These side-effects are likely to happen at the start of treatment, or with a change in the amount of Bisoprolol you take.

Bisoprolol contains:
Methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216): May cause allergic reactions (possibly delayed).
Sodium: This medicine contains less than 1 mmol sodium (23 mg) per 20 ml, that is to say essentially 'sodium-free'.

3. How to take Bisoprolol

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

Adults
Chest pain and high blood pressure (angina and hypertension)
Your doctor will start the treatment with the lowest possible dose (5 mg (10 ml)). Your doctor will monitor you closely at the start of treatment. Your doctor will increase your dose to obtain the best possible dosage for you.

The maximum recommended dose is 20 mg (40 ml) once per day.

Patients with kidney disease
Patients with severe kidney disease should not exceed 10 mg (20 ml) of Bisoprolol once daily. Please consult your doctor before starting to use this medicine.

Patients with liver disease
Patients with severe liver disease should not exceed 10 mg (20 ml) of Bisoprolol once daily. Please consult your doctor before starting to use this medicine.

Heart failure
Before you start using Bisoprolol oral solution, you should already be taking other medicines for heart failure including an ACE-inhibitor, a diuretic and (as an added option) a cardiac glycoside.

Treatment with Bisoprolol must be started at a low dose and increased gradually.
Your doctor will decide how to increase the dose, and this will normally be done in the following way:
- 1.25 mg (2.5 ml) Bisoprolol once daily for one week
- 2.5 mg (5 ml) Bisoprolol once daily for one week
- 3.75 mg (7.5 ml) Bisoprolol once daily for one week
- 5 mg (10 ml) Bisoprolol once daily for four weeks
- 7.5 mg (15 ml) Bisoprolol once daily for four weeks
- 10 mg (20 ml) Bisoprolol once daily for maintenance (on-going) therapy.

The maximum recommended daily dose is 10 mg (20 ml) Bisoprolol.

Depending on how well you tolerate the medicine, your doctor may also decide to lengthen the time between dose increases. If your condition gets worse or you no longer tolerate the drug, it may be necessary to reduce the dose again or to interrupt treatment. In some patients a

maintenance dose lower than 10 mg (20 ml) Bisoprolol may be sufficient.

Your doctor will tell you what to do.

Use in children and adolescents
The use of Bisoprolol is not recommended as there is insufficient experience with the use of this medicine in children and adolescents.

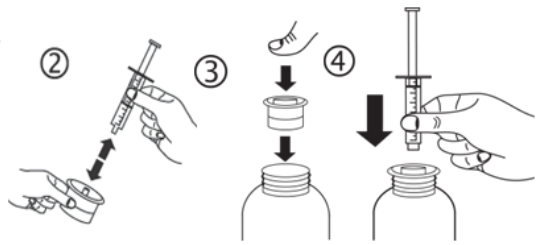
Elderly patients
In general an adjustment of the dose is not needed. It is recommended to start with the lowest possible dose.

If you notice that the Bisoprolol dose is too strong or does not work well enough, please consult your doctor or pharmacist.

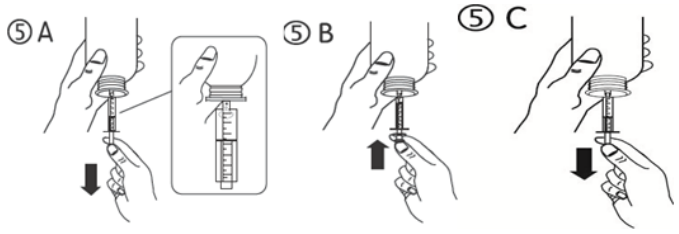
Route and Method of administration:
- ▶ Bisoprolol should be taken in the morning
- ▶ This medicinal product must be taken orally.
- ▶ Use the measuring syringe provided in the pack to deliver the required dose.
- ▶ Take Bisoprolol with or without food.

Instructions for the use of syringe:
a) Open the bottle: press the cap and turn it anticlockwise (figure 1).

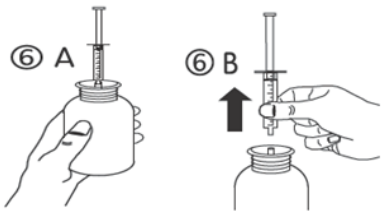
b) Separate the adaptor from the syringe (figure 2). Insert the adaptor into the bottle neck (figure 3). Ensure it is properly fixed. Take the syringe and put it in the adaptor opening (figure 4).



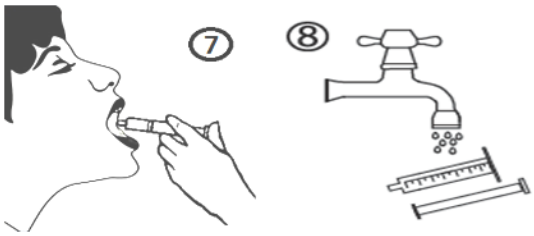
c) Turn the bottle upside down. Fill the syringe with a small amount of solution by pulling the piston down (figure 5A) and then push the piston up in order to remove any possible air bubbles (figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (figure 5C).



d) Turn the bottle the right way up (figure 6A). Remove the syringe from the adaptor (figure 6B). Once again check that pulled-up millilitres (ml) corresponds with the prescribed dose.



e) Empty the contents of the syringe into the mouth by pushing the piston to the bottom of the syringe (figure 7). The contents of the syringe should be emptied into the side cheek of the patient's mouth to avoid a choking hazard. Close the bottle with the plastic screw cap. Wash the syringe with water (figure 8).



If you take more Bisoprolol than you should
If you have taken more Bisoprolol than you should contact your doctor or casualty department **immediately.** Take the bottle of Bisoprolol with you.

If you forget to take Bisoprolol
Do not take a double dose to make up for a forgotten dose. Take the next dose on time. If you miss several doses, contact your doctor.

Symptoms of an overdose may include slowed heart rate, severe difficulty in breathing, feeling dizzy, or trembling (due to decreased blood sugar).

If you stop taking Bisoprolol
If you suddenly stop taking Bisoprolol you are likely to suffer from side effects. Your doctor will reduce your dose slowly over 2 weeks.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

To prevent serious reactions, speak to a doctor immediately if a side effect is severe, occurred suddenly or gets worse rapidly.

The following side effects are important and will require immediate action if you experience them. You should stop taking Bisoprolol and see your doctor immediately if the following symptoms occur.

Very common side effects (affecting more than 1 in 10 people):
- slow heart beat

Common side effects (affecting fewer than 1 in 10 people):
- worsening of heart failure causing increased breathlessness and / or retention of fluid if you have chronic heart failure.

Uncommon side effects (affecting fewer than 1 in 100 people):
- worsening of heart failure if you have hypertension or angina pectoris
- depression
- breathing problems in patients with asthma or chronic lung disease

Rare side effects (affecting fewer than 1 in 1,000 people):
- inflammation of the liver (hepatitis) causing abdominal pain, loss of appetite and sometimes jaundice with yellowing of the whites of the eyes and skin and dark urine
- Allergic reactions such as itching, redness and skin rash. Severe allergic reactions may involve face, neck, tongue, mouth or throat swelling, or difficulty breathing.

If you feel dizzy or weak, or have breathing difficulties please contact your doctor as soon as possible.

Further side effects are listed below according to how frequently they may occur:

Common side effects (affecting fewer than 1 in 10 people):
- cold hands and/or feet
- numbness of hands and/or feet
- low blood pressure
- feeling sick, vomiting, diarrhoea, constipation
- tiredness*
- headache*.

Uncommon side effects (affecting fewer than 1 in 100 people):
- worsening of irregular heart beat
- sleep disorder
- dizziness when standing up
- muscle weakness, muscle cramps.

Rare side effects (affecting fewer than 1 in 1,000 people):
- changes in blood test results
- reduced tear flow (can be a problem if you wear contact lenses)
- hearing disorders
- blocked, runny nose
- failure to get and maintain an erection (erectile dysfunction) nightmares
- hallucination (imagining things)

- fainting.

Very rare side effects (affecting fewer than 1 in 10,000 people):
- inflammation of the eye (conjunctivitis)
- aggravation of the skin condition psoriasis or the appearance of a similar dry, scaly rash
- hair loss.

* if treated for high blood pressure or angina then these symptoms occur especially at the beginning of treatment, or if your dosage changes. They are generally mild and often disappear within 1 to 2 weeks.

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

5. How to store Bisoprolol

- 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 bottle label and on the carton after EXP. The expiry date refers to the last day of that month.
- This medicinal product does not require any special storage conditions.
- Discard 60 days after first opening.
- Do not use this medicine if you notice that the solution becomes discoloured or shows any signs of deterioration. Seek the advice of your pharmacist.
- 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.

6. Contents of the pack and other information

What Bisoprolol oral solution contains
The active substance is bisoprolol fumarate.

Each ml oral solution contains 0.5 mg of bisoprolol fumarate.

The other ingredients are methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), sodium dihydrogen phosphate monohydrate (E339), disodium phosphate and purified water.

What Bisoprolol looks like and contents of the pack
Bisoprolol is a clear, colourless oral solution supplied in 150 ml amber glass bottle with tamper-evident child-resistant white (polyethylene/polypropylene) plastic cap with EPE liner. The pack also contains a 20 ml oral syringe with 5 ml graduation, 1 ml intermediate graduation and 0.5 ml sub graduation marks with an adaptor.

Marketing Authorisation Holder and Manufacturer:
Marketing Authorisation Holder:
Syri Pharma Limited
1 Windmill Lane

Dublin 2, D02 F206
Ierland

Manufacturer:
Pharmadox Healthcare Ltd.
KW20A Kordin Industrial Park,
Paola PLA 3000, Malta.

In het register ingeschreven onder: RVG 132206

This medicine is authorised in the Member States of the European Economic Area under the following name:
NL: Bisoprolol Syri Pharma 0,5 mg/ml, drank
IE: Bisoprolol Syri Pharma 0.5 mg/ml Oral solution

If this leaflet is hard to see or read, please call +353 1437 0882 for help.

Deze bijsluiter is voor het laatst goedgekeurd in december 2024.