Package leaflet: Information for the user

Soprol 5 mg Film-coated Tablets

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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Soprol is and what it is used for

Soprol belongs to a group of medicinal products called beta blockers. These products protect the heart against too much activity, which makes the heart more relaxed and reduces blood pressure.

Soprol is used for the treatment of:

- High blood pressure (hypertension).
- Chest pain (angina pectoris).

2. What you need to know before you take Soprol

Do not take Soprol:

- if you are allergic to Soprol or any of the other ingredients of this medicine (listed in section 6).
- If you suffer from a suddenly occurring heart weakness (acute heart failure) or deterioration of heart failure which require heart stimulating medicines to be administered directly into the vein.
- If you are in a state of shock caused by heart dysfunction.
- If you suffer from certain heart conduction disorders (2^{nd} or 3^{rd} degree AV-block without a pacemaker, sinoatrial block).
- If you suffer from certain heart rhythm disorders (sick sinus syndrome or sinoatrial block).
- If you have a slow heart rate (less than 60 beats per minute) before the start of the treatment.
- If you have a very low blood pressure (hypotension, systolic blood pressure of less than

100).
- If you suffer from severe forms of asthma or any other breathing problems such as chronic respiratory disorders (COPD).
- If you suffer from severe blood circulation problems in the fingers, toes, arms and legs, like Raynaud´s phenomenon. See also "Warnings and precautions".
- If you have a tumour of the adrenal medulla that may cause a severe high blood pressure (an untreated phaeochromocytoma). See also "Warnings and precautions".
- If you suffer from a condition where there is a change in the acid/base balance of the body (metabolic acidosis).
- If you are treated with floctafenine (a medicine used for relieving pain and swelling) or sultopride (a medicine used for the treatment of nervous system disorders). See also "**Other medicines and Soprol**".

Warnings and precautions
Talk to your doctor or pharmacist before taking Soprol:

- If you frequently suffer from lung disorders like asthma or respiratory disorders. In sensitive patients, Soprol can cause a narrowing of the airways; in this case your doctor will probably examine your lungs before the start of the treatment and possibly also prescribe a bronchodilator (or increase the dose thereof).
- If you are planning to undergo surgery. Your heart rate and blood pressure can change when anaesthetics are taken together with Soprol. Inform the anaesthetist that you are taking Soprol.
- If you have to undergo an X-ray examination with a contrast medium (so-called iodine containing contrast mediums). Inform your doctor that you are using Soprol.
- If you suffer from diabetes, as Soprol may hide the symptoms of low blood sugar (hypoglycaemia). Your blood glucose levels should be checked regularly. See also "Other medicines and Soprol".
- If you suffer from a thyroid problem, as Soprol may hide the symptoms of an overactive thyroid.
- If you are fasting.
- If you are treated for hypersensitivity reactions (anti-allergic treatments) or if you suffer from an allergic reaction. Soprol may potentiate the hypersensitivity to the substances you are allergic to and increase the severity of the allergic reactions.
- If you suffer from a heart conduction disorder (so-called 1st degree AV block)
- If you suffer from a tight, painful feeling in the chest at rest (Prinzmetal angina). Soprol may increase the number and the duration of the attacks.
- If you suffer from blood circulation problems in the fingers, toes, arms and legs (Raynaud's phenomenon) or a cramp like pain in the calves brought on by exercise or walking (intermittent claudication). The complaints may be worse, particularly at the beginning of the treatment.
- If you have a tumour of the adrenal medulla (phaeochromocytoma); Soprol may only be used in combination with certain medicinal products (the so-called alpha-blockers).
- If you suffer (or have suffered) from a recurrent skin disorder involving a scaling, dry skin rash (psoriasis).

At the beginning of the treatment your doctor will check you regularly (especially in the treatment of elderly patients).

Consult your doctor if one of the above mentioned warnings is applicable to you, or has been applicable in the past.

Children and adolescents
The use of Soprol is not recommended as there is insufficient experience with the use of this medicinal product in children.

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

Do not take Soprol in combination with:

- Floctafenine (a medicine used for relieving pain and swelling), as there is an increased possibility of reduced blood pressure or shock.
- Sultopride (a medicine used for the treatment of nervous system disorders), as there is an increased possibility of heart rhythm disorders.

Especially tell your doctor if you are taking one of the following drugs because if Soprol is used in combination with the products mentioned below the possibility of side effects on the heart and / or changes in the blood pressure is increased.

- Medicines used to treat heart rhythm disorders and high blood pressure, such as calcium antagonists (verapamil, diltiazem and bepridil).
- Medicines used to treat high blood pressure such as clonidine and other blood pressure reducing medicines that work by affecting the part of the brain that controls blood pressure, such as methyldopa, guanfacine, moxonidine and rilmenidine.
- Any other drugs used for high blood pressure treatment.
- Medicines used to treat severe depression such as the so-called MAO-A inhibitors (moclobemide).
- medicines used for the treatment of heart rhythm disorders such as the so-called anti-arrhythmics class I (e.g. disopyramide and quinidine) and anti-arrhythmics class III (e.g. amiodarone).
- Medicines used to treat a tight, painful feeling in the chest and high blood pressure such as calcium antagonists (nifedipine and amlodipine (so-called dihydropyridine derivatives)).
- Medicines used for the treatment of Alzheimer's disease such as acetyl cholinesterase inhibitors (rivastigmine, galantamine and tacrine).
- Other beta-blockers such as atenolol or metoprolol.
- Eye drops that contain beta-blockers such as timolol or betaxolol.
- Medicines used for the treatment of heart weakness and certain heart rhythm disorders such as digitalis glycosides (digoxin).
- Anesthetics, such as propofol and lidocaine. See also the section on “Warnings and precautions”.
- Medicines used in the treatment for severe depression such as tricyclic antidepressants (amitriptyline or clomipramine).
- Medicines used to treat severe mental illness such as phenothiazines (chlorpromazine or perphenazine).
- Medicines used for the treatment of epilepsy such as barbiturates (phenobarbital).
- Other blood pressure reducing medicines.
- The muscle relaxant baclofen.

- Medicines used to protect the body against the consequences of certain treatments of cancer such as amifostine.
- The antimalarial drug mefloquine.
- Medicines used to control the immune system and symptoms of inflammation such as corticosteroids.
- Medicines used for treatment of diabetes such as insulin, metformin and tolbutamide; Soprol may enhance the glucose reducing effect of these products and may hide the symptoms of a low blood sugar level in your blood. See also “Warnings and precautions”.
- Medicines used to treat migraines such as Ergotamine, as it may increase the blood flow disorders in the arms and legs.
- Medicines that cause a stimulating effect on a certain part of the nervous system such as beta-sympatheticomimetics (dobutamine and isoprenaline). Taking these medicines with Soprol may reduce the effect of both products.
- A certain group of pain killers (the so-called NSAIDs), such as ibuprofen, naproxen and diclofenac; these may reduce the effect of Soprol.
- drugs for treatment of Alzheimer's disease (donepezil).
- Drugs for the treatment of a disease called miasthenia gravis (neostigmin).

Pregnancy, breast-feeding and 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.

Soprol 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 this medicinal product is not recommended during pregnancy.
It is unknown if Soprol is excreted in the breast milk. Breast-feeding during the use of this medicinal product is therefore not recommended.

Driving and using machines

The use of Soprol 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 that require your full attention. Attention is in particular required at the beginning of the treatment, with changes in medication and with use in combination with alcohol.

3. How to take Soprol

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

The tablets can best be taken with an ample amount of water (1 glass). The recommended dose is

Adults
Initial dose: Your doctor will start the treatment with the lowest possible dose. Sometimes 5 mg per day (24 hours) can be sufficient.
The usual maintenance dose is 10 mg once per day. The maximum recommended dose is 20 mg per day.

Use in children and adolescents
The use of Soprol is not recommended as there is insufficient experience with the use of this medicinal product in children.

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

Patients with a severely reduced kidney function
The maximum dose is 10 mg per day (24 hours). This dose can possibly be distributed in 2 administrations.

Patients with a severely reduced liver function
The maximum dose is 10 mg per day (24 hours).

If you take more Soprol than you should

If you have taken too much Soprol, contact your doctor or pharmacist immediately. Symptoms that may occur when taking a dose that is too high are, reduced heart rate, reduced blood pressure, shortness of breath, insufficient action of the heart and a low blood glucose level (involving feelings of hunger, sweating, dizziness and palpitations). In severe cases the doctor will possibly flush out your stomach (gastric lavage).

If you forget to take Soprol

If you have missed a dose, then take this dose as quickly as possible. However, if it is almost time for the next dose, skip the missed dose and continue on your normal dosing schedule. Never take a double dose of Soprol to make up for a forgotten dose.

If you stop taking Soprol

If you suddenly stop the use of Soprol an exacerbation of a disorder of the heart may occur or your blood pressure may become high again. Therefore, it is better not to suddenly discontinue the use of this medicinal product. Your doctor will gradually reduce the dose.

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.

If you feel one of the following, stop taking Soprol and go to your doctor or the nearest hospital straight away:
- increased breathlessness and swelled legs which are the symptoms of a reduced action of the heart (heart failure) (this side effect may affect up to 1 in 100 people)

- Shortness of breath and wheezing due to narrowing of the airways in patients with asthma or disorders of the airways (bronchospasm) (this side effect may affect up to 1 in 100 people)
- Hypersensitivity reactions such as itching, redness of the skin, skin rash and swelling (face, hands, feet), difficulty breathing (this side effect may affect up to 1 in 1000 people)
- Fever, tiredness, painfull joints, face rash which are syptoms of a disease called lupus syndrome (this side effect may affect up to 1 in 1000 people)
- yellow discolouration of the skin or eyes (jaundice), drak urine, tiredness and belly pain which are signs of inflammation of the liver (hepatitis) (this side effect may affect up to 1 in 1000 people)
- observations of things that are not present (hallucinations) (this side effect may affect up to 1 in 1000 people)
- Worsening of a recurrent skin disorder involving scaling, dry skin rash (psoriasis) (this side effect may affect up to 1 in 1000 people)

Amongst others the following side effects can occur:

Very common: may affect more than 1 in 10 people

- Tiredness, dizziness or headache (these side effects occur especially at the beginning of the treatment and are generally mild in nature and often disappear within 1-2 weeks).
- Cold hands and/or feet, numbness of hands and/or feet, exacerbation of the pain in the legs and limping (intermittent claudication, Raynaud's Phenomenon).
- Nausea, vomiting, diarrhoea, abdominal pain or constipation.
- Hypotension (low blood pressure).

Uncommon: may affect up to 1 in 100 people

- Reduced heart rate, exacerbation of existing rhythm disorders such as AV-block
- Blood pressure reduction, for instance due to standing up quickly from a sitting or supine position, sometimes involving dizziness (orthostatic hypotension)
- Depression
- Muscle weakness and muscle cramps, joint problems
- Sleep disorders
- (malaise)

Rare: may affect up to 1 in 1,000 people

- Increase in liver enzymes (AST, ALT) which can be seen in blood test
- Low blood glucose level (hypoglycemia) involving feelings of hunger, sweating, dizziness, palpitations
- Increase in a type of fat found in the blood (triglycerides)
- Male impotence
- Inflammation of the nasal mucous membrane characterised by a blocked up nose, sneezing (allergic rhinitis)
- Dry eyes (can be very troublesome when you are wearing contact lenses)
- Nightmares
- Hearing disorders
- fainting

Very rare: may affect up to 1 in 10,000 people

- Hair loss
- Inflammation of the eye or eyelid (Conjunctivitis)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail:medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Soprol

Keep this medicine out of the sight and reach of children.

Bottle: Do not store above 25°C, store in the tightly closed container in order to protect from light and/or moisture.
Blister strips: Do not store above 25°C, store in the original container in order to protect from light and/or moisture.

Do not use this medicine after the expiry date which is stated on the package after “do not use after” or "exp.". The expiry date refers to the last day of that month.

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 Soprol 5 mg Film-coated Tablets contains

The active substance is Bisoprolol fumarate: 5 mg per tablet.
The other ingredients are
Core: microcrystalline cellulose (E460i), mannitol (E421), sodium croscarmellose (E466), magnesium stearate (E572);
Coating: hypromellose (E464), titanium dioxide (E171), macrogol 6000.

What Soprol 5 mg Film-coated Tablets looks like and contents of the pack

Soprol 5 mg Film-coated Tablets are white, round, convex coated tablets and contain the inscription BISOPROLOL 5 on one side of the 5 mg Tablet.

The tablets are packaged in a blister strip of 20, 28, 30, 50, 56, 60, 84, 90, 98, 100 and 105 each, in unit dose packages of 50 each and in bottles of 20, 28, 30, 50, 56, 60, 84, 90, 98, 100 and 105 each.
Not all pack sizes may be marketed.

Marketing Authorisation Holder

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This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium	Bisoprolol TEVA 5 mg filmomhulde tabletten
France	Bisoprolol TEVA 5 mg, comprimé pelliculé
Germany	Bisoprolol-TEVA® 5 mg Filmtabletten
Ireland	Soprol® 5 mg Film-coated Tablets
Spain	Bisoprolol TEVA 5 mg comprimidos recubiertos con pelicula
The Netherlands	Bisoprololfumaraat 5 PCH, omhulde tabletten 5 mg
United Kingdom	Bisoprolol Fumarate 5 mg Film-coated Tablets

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