

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PRESESE 5 mg TABLETS (tablet)

PRESESE 10 mg TABLETS (tablet)

Bisoprolol fumarate (2:1)

Sugar free

Read all of this leaflet carefully before you start taking PRESESE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **PRESESE** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What **PRESESE** is and what it is used for
2. What you need to know before you take **PRESESE**
3. How to take **PRESESE**
4. Possible side effects
5. How to store **PRESESE**
6. Contents of the pack and other information

1. What PRESESE is and what it is used for

PRESESE belongs to a group of medicines called beta-blockers.

PRESESE is used in combination with other medicines to treat stable chronic (long-term) moderate to severe heart failure.

2. What you need to know before you take PRESESE

Do not take PRESESE:

- If you are hypersensitive (allergic) to bisoprolol, or any of the other ingredients of **PRESESE** (listed in section 6).
- If you are in acute heart failure or if you require injection of inotropic medicines (medicines which increase the force of contraction of the heart)
- If you have had cardiac shock (inadequate heart function)
- If you suffer from heart block and do not have a pacemaker
- If you suffer from very slow heartbeats (less than 50/minute) or sick sinus syndrome (a syndrome of slow heart beats with rapid dysrhythmics)
- If you suffer from sinoatrial block (interference of impulse to heart chamber)
- If you have very poor circulation or Raynaud's syndrome
- If you have low blood pressure
- If you suffer from an untreated phaeochromocytoma (a tumour on the adrenal glands)
- If you suffer from severe bronchial asthma, bronchitis or have severe breathing difficulties.
- If you are pregnant or breast-feeding.
- If you suffer from an overactive thyroid gland producing an excessive amount of thyroid hormones.
- If you have metabolic acidosis (a condition that occurs when the body produces too much acid or when the kidneys are not removing enough acid from the body)
- In children.

Warnings and precautions

Special care should be taken with PRESESE:

- Before taking **PRESESE**, tell your doctor if you suffer from any of the following:
 - asthma or any other lung disease.
 - diabetes mellitus (taking **PRESESE** can make it harder for you to tell when you have low blood sugar)
 - you are having desensitisation therapy for allergies

- heart problems or first degree heart block (a condition in which nerve signals to the heart are disturbed, possibly causing it occasionally to skip a beat, or beat irregularly).
irregular heartbeat, sudden onset of chest pain, suffer from a mild form of angina and Prinzmetal's angina (a form of unstable angina)
- poor circulation
- psoriasis
- kidney disease – If you have severe kidney problems, your doctor will adjust the dosage of **PRESESE**.
- a pheochromocytoma (a tumour on the adrenal glands)
- Also tell your doctor if:
 - you are fasting
 - you are taking or receiving any other medicines such as anaesthetics, calcium antagonists, medicines used to treat heart disease and irregular heartbeat such as disopyramide and verapamil, and clonidine (medicine used to treat high blood pressure, migraine and menopausal flushing).Care is required if you are being transferred from clonidine to **PRESESE**. If you are taking **PRESESE** and clonidine together, the clonidine should not be stopped until several days after **PRESESE** have been withdrawn.
- you need to have any type of surgery. Tell the surgeon and anaesthetist ahead of time that you are using **PRESESE**.
- If you are elderly (over the age of 60 years).
- **PRESESE** may mask the signs of thyroid overactivity.
- Your doctor will monitor you regularly when you start taking **PRESESE**.
- If you have a history of severe allergic reactions that have required adrenaline, **PRESESE** may make your system unresponsive to the usual effective dose of adrenaline.
- **Stopping treatment with PRESESE:** Do not stop treatment suddenly without talking to your doctor first.

Children and adolescents

Safety and efficacy in children have not been established.

Taking PRESESE with food and drink:

- **PRESESE** can be taken with food.
- Swallow the tablets with liquid.

Pregnancy, breastfeeding and fertility

PRESESE must not be taken during pregnancy and breastfeeding.

Taking **PRESESE** shortly before birth or during labour may cause decreased muscle tone (floppiness) and low blood sugar in the newborn.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machinery:

PRESESE may cause drowsiness and dizziness. Do not drive or use any tools or machines until you know how the tablets affect you.

It is not always possible to predict to what extent **PRESESE** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **PRESESE** affects them.

Other medicines and PRESESE

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

- Before taking **PRESESE TABLETS**, tell your doctor if you are using any of the following medicines:

- Oral medicines used to treat diabetes and insulin.
- Phenothiazines (treatment of psychotic disorders)
- Medicines used to treat dysrhythmias (irregular heartbeats) e.g. disopyramide, feldopine, flecainide, propafenone or quinidine. Medicines used to treat acute heart problems (such as isoprenaline, dobutamine) may antagonise the effects of **PRESESE**.

- Sympathomimetics such as epinephrine and norepinephrine which are used in the treatment of heart attack and low blood pressure. Epinephrine is also used to treat allergic reactions. Higher doses of adrenaline may be necessary for treatment of allergic reactions if **PRESESE** is taken at the same time.
- Medicines used to treat high blood pressure (such as clonidine, digitalis, glycosides, diltiazem, methyldopa, moxonidine and rilmenidine) may further decrease heart rate when taken with **PRESESE**. However, do not stop taking these medicines without checking with your doctor first.
- Using certain medicines (such as reserpine or guanethidine) causing high blood pressure together with **PRESESE** may cause life-threatening vasoconstriction (constricting of the blood vessels).
Digoxin (medicine for heart failure) may be used with **PRESESE**. Your doctor should monitor your pulse rate and response regularly.
- Anaesthetics
- Rifampicin (antibiotic to treat TB)
- Dihydropyridine-type calcium antagonists, such as nifedipine and amlodipine, used to treat high blood pressure or angina pectoris.
- Dihydropyridine-type calcium antagonists, such as nifedipine and amlodipine, used to treat high blood pressure or angina pectoris. Calcium channel blocker medicines (e.g. verapamil) (medicine for angina and high blood pressure)
- Clonidine (medicine for high blood pressure)
- Barbiturates (used for insomnia)
- Monoamine oxidase inhibitors (e.g. phenelzine, selegeline, tranylcypromine) (medicine used to treat depression)
- Medicines which can result in the lowering of blood pressure (e.g. medicines specifically given to lower blood pressure, certain medicines for depression (tricyclic antidepressants such as imipramine or amitriptyline), during anaesthesia (lidocaine) or epilepsy (phenytoin or barbiturates such as phenobarbital).
- Prostaglandin synthetase inhibitors (e.g. indomethacin)
- Ergotamine (medicine for migraines)

- Tacrine
- Other beta-blocker medicines, including eye drops. Beta-blockers applied locally (such as timolol eye drops to treat glaucoma).
- Medicines used to treat high blood pressure.
- Halofantrine, mefloquine and quinine used for the prevention or treatment of malaria.
- Medicines used to treat conditions such as Alzheimer's disease or glaucoma (known as parasympathomimetics) such as tacrine or carbachol.
- Non-steroidal anti-inflammatory medicines (NSAID's) used to treat arthritis, pain or inflammation (e.g. ibuprofen or diclofenac.). These medicines may reduce the effects of **PRESESE**.
- Moxisylyte which is used to treat circulatory problems like Raynaud's syndrome.
- Ergotamine derivatives used in the acute treatment of migraine headaches.
- Medicines for asthma or medicines used for a blocked nose.

If you are using any of these medicines, you may not be able to take **PRESESE**, or you may need dosage adjustments or your doctor may need to monitor you carefully for side-effects.

- Before you stop taking any of your medicines, please talk to your doctor first.

3. How to take PRESESE

Do not share medicines prescribed for you with any other person. Always take **PRESESE** exactly as your doctor has instructed you. Your doctor will tell you how long your treatment with **PRESESE** will last. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **PRESESE** is too strong or too weak, talk to your doctor or pharmacist.

- Your doctor will tell you how many tablets to take. You should take **PRESESE** in the morning.
PRESESE can be taken with food.
- Swallow the tablet/s with some liquid and do not chew or crush them.

Adults and the elderly:

When you first start taking **PRESESE** your doctor will increase the strength of the tablets you take gradually, until you receive the dose that suits you best.

Your doctor will usually start your treatment with: **PRESESE** 1.25 mg, once daily.

If you take more PRESESE than you should:

Overdose symptoms may include slow heart rate and severe low blood pressure.

Wheezing or shortness of breath and heart failure may occur.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take PRESESE:

Do not take a double dose to make up for a missed dose. Take the normal dose as soon as you remember and then carry on with the usual dose the next day.

Effects when treatment with PRESESE is stopped:

Stopping treatment with PRESESE: Do not stop treatment suddenly or change the recommended dose without talking to your doctor first. If you need to stop treatment, it is usually done gradually, to avoid side effects.

4. Possible side effects

PRESESE can have side effects.

Tell your doctor if any of the above side-effects are severe, bothersome, do not go away or about any concerns you have while taking **PRESESE**.

Not all side-effects reported for **PRESESE** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **PRESESE**, please consult your doctor, pharmacist or other health care professional for advice.

PRESESE can have side-effects.

Get emergency medical help if you have any of these **signs of an allergic reaction**:

- Hives/rash; difficulty breathing; swelling of your face, lips, tongue, or throat.

Call your doctor at once if you have any of these serious side-effects:

- Slow, fast or pounding heartbeats

- Chest pain
- Dizziness, light headedness or fainting
- Feeling short of breath, even with mild exertion
- Swelling of ankles, feet, or lower legs
- Unusual bleeding or bruising
- Hallucinations (false perceptions), loss of contact with reality
- Numbness, tingling, or cold feeling in your hands and feet.
- Too few white blood cells; lack of energy, fatigue, lethargy.
- Bronchospasm (constriction of air passages causing difficulty in breathing).
- Hepatitis (inflammation of the liver) - characterised by yellowing of your skin or the whites of your eyes).

You may notice tiredness, exhaustion, dizziness and headache, especially during the first two weeks of treatment.

Other side effects include:

Frequent:

- Fatigue, unusual tiredness or weakness.
- Feeling short of breath, even with mild exertion
- Mild headache
- Sweating
- Low blood pressure
- High blood pressure
- Nausea (queasiness, feeling that one is about to vomit)
- Vomiting
- Diarrhoea (frequent or loose watery stools)
- Constipation
- Decreased sexual ability

Less frequent

- Difficulty in sleeping
- Restlessness

- Depression
- Problems with vision
- Skin reactions (rash, itching)
- Loss of hair
- Restlessness
- Inflammation of the mouth
- Problems with hearing
- Muscle cramps
- Muscle weakness
- Weight gain
- Low blood sugar
- Increased levels of uric acid in the blood
- Increased blood levels of some fats
- Light headedness or fainting (especially when getting up from a lying down position)
- Nightmares
- Increased liver enzymes (you would notice yellowing of your skin or the whites of your eyes)
- Impotence (loss of male sexual ability)
- Runny nose
- Dry eyes, changes in vision
- Conjunctivitis.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **PRESESE**.

5. How to store PRESESE

Store at or below 25 °C (room temperature). Protect from light and moisture.

Do not remove the blister strip from the carton until required for use. Keep the container well closed.

Store all medicines out of the reach and sight of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Contents of the pack and other information

What PRESESE contains:

The active substance is bisoprolol fumarate.

PRESESE 5 mg TABLETS:

Each film-coated tablet contains bisoprolol fumarate (2:1) 5 mg. Sugar free.

PRESESE 10 mg TABLETS:

Each film-coated tablet contains bisoprolol fumarate (2:1) 10 mg. Sugar free.

The other ingredients of **PRESESE** are calcium hydrogen phosphate; cellulose microcrystalline; crospovidone; magnesium stearate and silica colloidal anhydrous. The coating material of **PRESESE** contains hypromellose; macrogol / PEG 400 and titanium dioxide (C.I. No: 77891), purified water, iron oxide yellow.

What PRESESE looks like and contents of the pack

PRESESE 5 mg AND PRESESE 10 mg TABLETS:

Blister pack:

Tablets are packed in printed peelable lidding silver foil (50 g/m² paper / 12 micron polyster / 20 micron Aluminium foil / 7 g/m² HSL) and cold form film (25 micron polyamide / 45 micron Aluminium foil / 60 micron PVC film). One blister contains 10 tablets.

Pack size: 30's: Each carton contains 3 blisters of 10 tablets each.

HDPE Container Pack:

Applicant/PHCR: AUROGEN SOUTH AFRICA (PTY) LTD
Product proprietary name: PRESESE 5 mg / 10 mg TABLETS
Dosage form and strength: TABLET 5 mg / 10 mg

Date: 19/12/2024

Tablets are packed in white opaque round 40 ml HDPE container with a white opaque ribbed stock (RS) HDPE closure, with induction sealing wad containing one silica gel sachet. Each container which is enclosed in an outer cardboard carton contains 30 tablets.

Pack size: 30's - One HDPE container contains 30 tablets.

Identification of PRESESE

PRESESE 5 mg TABLETS:

Yellow coloured, circular, biconvex, film-coated tablets, debossed with 'I and break line' on one side and '11' on the other side.

PRESESE 10 mg TABLETS:

Yellow coloured, circular, biconvex, film-coated tablets, debossed with 'I and break line' on one side and '13' on the other side.

Registration Number/Reference Number

PRESESE 5 mg TABLETS: 45/5.2/0866

PRESESE 10 mg TABLETS: 45/5.2/0867

Holder of Certificate of Registration

Aurogen South Africa (Pty) Ltd.
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