

PATIENT INFORMATION LEAFLET

Asomex 5 mg Tablet

S (-) Amlodipine Besilate Tablets 5 mg

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care provider or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

In this leaflet:

a) WHAT ASOMEX IS AND WHAT IT IS USED FOR

b) BEFORE YOU TAKE ASOMEX

c) HOW TO TAKE ASOMEX

d) POSSIBLE SIDE EFFECTS

e) HOW TO STORE ASOMEX

f) FURTHER INFORMATION

a) WHAT ASOMEX IS AND WHAT IT IS USED FOR

Asomex contains the active substance s (-) amlodipine which belongs to a group of medicines called calcium channel blockers.

Asomex is used to treat high blood pressure (hypertension) or a certain type of chest pain called angina. In patients with high blood pressure your medicine works by relaxing blood vessels, so that blood passes through them more easily. In patients with angina, s-amlodipine works by improving blood supply to the heart muscle which then receives more oxygen and as a result chest pain is prevented. This medicine does not provide immediate relief of chest pain from angina.

b) BEFORE YOU TAKE ASOMEX

Do not take Asomex if:

- If you are allergic (hypersensitive) to amlodipine, or any of the other ingredients of your medicine listed in section 6, or to any other calcium antagonists. This may be itching, reddening of the skin or difficulty in breathing.
- If you have severe low blood pressure (hypotension).
- If you have narrowing of the aortic heart valve (aortic stenosis) or cardiogenic shock (a condition where your heart is unable to supply enough blood to the body).
- If you suffer from heart failure after a heart attack.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Take special care with Asomex

Talk to your doctor or pharmacist before taking this medicine.

You should inform your doctor if you have or have had any of the following conditions:

- Recent heart attack
- Heart failure
- Severe increase in blood pressure (Hypertensive crisis)
- Liver disease
- You are elderly

Taking other medicines

Please tell your doctor, health care provider or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

In particular, tell your doctor if you are taking any of the following medicines:

- ketoconazole, itraconazole (anti-fungal medicines)
- ritonavir, indinavir, nelfinavir (so called protease inhibitors used to treat HIV)
- rifampicin, erythromycin, clarithromycin (antibiotics)
- hypericum perforatum (St. John's Wort)
- verapamil, diltiazem (heart medicines)
- dantrolene (infusion for severe body temperature abnormalities)
- tacrolimus, sirolimus, temsirolimus and everolimus (medicines used to alter the way your immune system works)
- simvastatin (a cholesterol lowering medicine)
- cyclosporine (an immunosuppressant)

Asomex may lower your blood pressure even more if you are already taking other medicines to treat your high blood pressure.

Taking Asomex with food and drink

Grapefruit juice and grapefruit should not be consumed by people who are taking Asomex. This is

because grapefruit and grapefruit juice may lead to an increase in the blood levels of the active ingredient amlodipine, which can cause an unpredictable increase in the blood pressure lowering effect of Asomex.

Pregnancy and breast-feeding

Ask your doctor, health care provider or pharmacist for advice before taking any medicine.

Pregnancy

Your treating doctor will decide whether to continue this medicine or use other medicine depending on your clinical situation. Ask your doctor or pharmacist for advice before taking any other medicine.

Breast-feeding

If you are breast-feeding or about to start breast-feeding, you must tell your doctor before taking this medicine.

Your treating doctor will decide whether to continue this medicine during breast feeding depending on your clinical situation and importance of this medicine to you.

Driving and using machines

Asomex may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

c) HOW TO TAKE ASOMEX

Always take Asomex exactly as your doctor or pharmacist has told you. You should check with your doctor, healthcare provider or pharmacist if you are not sure.

Your doctor will decide the dose which is best for you. Always follow your doctor's instructions exactly. The usual initial dose is Asomex 2.5 mg once daily. The dose can be increased to Asomex 5 mg once daily.

This medicine can be used before or after food and drinks. You should take this medicine at the same time each day with a drink of water. Do not take s-amlodipine with grapefruit juice.

Use in children

Asomex has not been studied in children and adolescents and therefore not recommended.

If you forget to take Asomex

Do not take a double dose to make up for a forgotten dose.

If you stop taking Asomex

If you have any further questions on the use of this medicine, ask your doctor, healthcare provider or pharmacist.

d) POSSIBLE SIDE EFFECTS

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

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

The side-effects experienced with racemic amlodipine may also occur with s-amlodipine and the same has been discussed below:

Visit your doctor **immediately** if you experience any of the following very rare, severe side effects after taking this medicine.

- Sudden wheeziness, chest pain, shortness of breath or difficulty in breathing
- Swelling of eyelids, face or lips
- Swelling of the tongue and throat which causes great difficulty breathing
- Severe skin reactions including intense skin rash, hives, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, inflammation of mucous membranes (Stevens Johnson Syndrome) or other allergic reactions
- Heart attack, abnormal heart beat
- Inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell

Other side-effects

Very common: may affect more than 1 in 10 people

- oedema (fluid retention)

The following **common side-effects** have been reported. If any of these cause you problems or if they **last for more than one week**, you should **contact your doctor**.

Common: may affect up to 1 in 10 people

- Headache, dizziness, sleepiness (especially at the beginning of treatment)
- Palpitations (awareness of your heart beat), flushing
- Abdominal pain, feeling sick (nausea)
- Altered bowel habits, diarrhoea, constipation, indigestion
- Tiredness, weakness
- Visual disturbances, double vision
- Muscle cramps
- Ankle swelling

Other side-effects that have been reported include the following list. If any of these get serious, or

if you notice any side-effects not listed in this leaflet, please tell your doctor or pharmacist.

Uncommon: may affect up to 1 in 100 people

- Mood changes, anxiety, depression, sleeplessness
- Trembling, taste abnormalities, fainting
- Numbness or tingling sensation in your limbs; loss of pain sensation
- ringing in the ears
- Low blood pressure
- Sneezing/running nose caused by inflammation of the lining of the nose (rhinitis)
- cough
- Dry mouth, vomiting (being sick)
- Hair loss, increased sweating, itchy skin, red patches on skin, skin discoloration
- Disorder in passing urine, increased need to urinate at night, increased number of times of passing urine
- Inability to obtain an erection, discomfort or enlargement of the breasts in men
- pain, feeling unwell
- Joint or muscle pain, back pain
- Weight increase or decrease

Rare: may affect up to 1 in 1000 people

- Confusion

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

Decreased numbers of white blood cells, decrease in blood platelets which may result in unusual

bruising or easy bleeding

- Excess sugar in blood (hyperglycaemia)
- A disorder of the nerves which can cause weakness, tingling or numbness
- Swelling of the gums
- Abdominal bloating (gastritis)

- Abnormal liver function, inflammation of the liver (hepatitis), yellowing of the skin (jaundice), liver enzyme increase which may have an effect on some medical tests
- Increased muscle tension
- Inflammation of blood vessels, often with skin rash
- Sensitivity to light
- Disorders combining rigidity, tremor, and/or movement disorders

Not known: frequency cannot be estimated from the available data

Trembling, rigid posture, mask-like face, slow movements and a shuffling, unbalanced walk

During post-marketing, the following adverse events were reported with Asomex:

Diarrhoea, oedema, edematous feet or pedal edema, stomach pain, swelling of ankles, feet, legs and limbs, bilateral legs ankle region with feet pitting edema, dizziness, hypertension, fever, frequent urination, fall, ear buzzing, hands trembled, headache, hoarseness, feeling abnormal, depression, swallowing difficulty, sleeping difficulty, weight loss, blood pressure increased, generalised anxiety disorder, gastro intestinal bleeding, increased urinary frequency, cough, racing thoughts, fractures on the brain, overdose, body paraesthesia, boiling sensation of the body, facial swelling, warm hands, accelerated heart rate, tooth infection, burning tongue, depression, dysphagia, erectile dysfunction, skull fracture, sleepy, and spike in blood sugar level.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

e) HOW TO STORE ASOMEX

Keep out of the reach and sight of children.

Do not use Asomex after the expiry date which is stated on the carton and bottle after EXP. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Store in a dry place, below 30 °C.

f) FURTHER INFORMATION

What Asomex contains

- The active substance(s) is S (-) Amlodipine Besilate

- The other ingredient(s) is (are)...

- Microcrystalline Cellulose USP
- Yellow oxide of Iron In house
- Croscarmellose Sodium USP NF
- Colloidal Silicon Dioxide USP NF
- Magnesium Stearate BP

What Asomex looks like and contents of the pack

10 Tablet pack in blister pack (PVDC coated PVC/ Aluminum Foil). 3 such blisters of 10 tablets each are packed in a carton along with pack insert.

Name and full physical address of Marketing Authorization Holder and Manufacturing site:

Emcure Pharmaceuticals Limited

Plot No. P-1 & P-2, IT-BT Park, Phase-II, M.I.D.C.,

Hinjawadi, Pune-411057, Maharashtra, India.

DOCUMENT REVISION HISTORY

23/05/2024