

PATIENT INFORMATION LEAFLET
ASOMEX 2.5/5 – ORAL TABLET
s (-) amlodipine 2.5mg/5 mg

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

- 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. 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 or pharmacist.

In this leaflet:

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

1. 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.

2. What you need to know before you take ASOMEX

Do not take ASOMEX

- 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.

Warnings and Precautions

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

Use in children and adolescents

Safety and effectiveness of this product in children have not been established.

Other medicines and ASOMEX

Tell your doctor 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.

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

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.

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.

Use in children and adolescents

Safety and effectiveness of s-amlodipine has not been established in children. For more information, talk to your doctor.

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.

Important information about some of the ingredients of ASOMEX

This medicine contains less than 1 mmol sodium (23 mg) per tablet, which means it is essentially 'sodium-free'.

3. HOW TO TAKE ASOMEX

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor 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 and adolescents

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

If you take more ASOMEX than you should

Taking too many tablets may cause your blood pressure to become low or even dangerously low.

You may feel dizzy, lightheaded, faint or weak. If blood pressure drop is severe enough shock can occur.

Your skin could feel cool and clammy and you could lose consciousness. Seek immediate medical attention if you take too many ASOMEX tablets.

If you forget to take ASOMEX

Do not worry. If you forget to take a tablet, leave out that dose completely. Take your next dose at the right time. Do not take a double dose to make up for a missed dose.

If you stop taking ASOMEX

Your doctor will advise you how long to take your medicine. Your condition may return if you stop using your medicine before you are advised.

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

4. Possible side effects

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

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

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

Diarrhoea, oedema, swelling of ankles, feet and legs, dizziness, hypertension, fever, frequent urination, fall, ear buzzing, headache, hoarseness, feeling abnormal, depression, swallowing difficulty, sleeping difficulty, weight loss, generalised anxiety disorder, cough, racing thoughts, fractures on the brain, overdose, body paraesthesia, boiling sensation of the body, facial swelling, warm hands, accelerated heart rate.

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.

5. How to store ASOMEX

Store in a dry place, below 25°C.

Keep out of the reach and sight of children.

Do not use this medicine after the expiry date which is stated on the Label after '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

10 Tablets are packed in blister pack (Amber coloured PVDC coated PVC film / VMCH Coated Aluminium foil). 3 such blisters of 10 tablets each are packed in a printed carton along with leaflet.

What ASOMEX contains

Amlodipine Besilate

Microcrystalline cellulose

Colloidal silicon dioxide

Yellow oxide of Iron

Croscarmellose sodium

Magnesium stearate

What ASOMEX looks like and contents of the pack

ASOMEX is faint yellow coloured heart shaped uncoated tablets with break line on one side.

10 Tablets are packed in blister pack (Amber coloured PVDC coated PVC film / VMCH Coated Aluminium foil). 3 such blisters of 10 tablets each are packed in a printed carton along with leaflet.

Marketing Authorization Holder and Manufacturer

Emcure Pharmaceuticals Limited