

PATIENT INFORMATION LEAFLET

ASOMEX D

s (-) Amlodipine Besilate 2.5mg & Hydrochlorothiazide 12.5 mg Tablets

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

1. What Asomex D is and what it is used for

Asomex D contains the active substance S (-) amlodipine besilate which belongs to a group of medicines called calcium channel blockers and hydrochlorothiazide is a diuretic.

Asomex D is used to treat high blood pressure (hypertension). In patients with high blood pressure your medicine works by relaxing blood vessels, so that blood passes through them more easily.

Hydrochlorothiazide works by making the kidneys pass more water and salt. This also helps to reduce blood pressure

2. What you need to know before you take Asomex D

Do not take Asomex D

- If you are allergic (hypersensitive) to amlodipine, sulphonamide-derived substances (as hydrochlorothiazide) or any of the other ingredients of your medicine listed in section 6.
- 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.
- if you have low potassium, low sodium or high calcium levels which cannot be corrected by treatment
- if you have severely impaired liver function
- if you are suffering from gout, defective metabolism of uric acid
- if you have severely impaired kidney function or your kidneys are not producing any urine,

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
- Liver and/or kidney disease
- You are elderly
- Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.
- if you are a diabetic
- if you have had gout
- if you have high calcium or low potassium levels or you are on a low potassium diet
- if you experienced breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past. If you develop any severe shortness of breath or difficulty breathing after taking this medicine, seek medical attention immediately;
- if you need to have an anaesthetic (even at the dentist) or before surgery, or if you are going to have tests to check your parathyroid function, you must tell the doctor or medical staff that you are taking Asomex D;
- If you experience a decrease in vision or eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to weeks of taking this medicine. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulfonamide allergy, you can be at higher risk of developing this.
- if you have had skin cancer or if you develop an unexpected skin lesion during the treatment. Treatment with hydrochlorothiazide, particularly long term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking this medicine
- if you have or have had an allergic condition, asthma or a condition that causes joint pain, skin rashes and fever (systemic lupus erythematosus).

Use in children and adolescents

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

Other medicines and Asomex D

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)
- Preparations containing lithium should not be taken with this medicine without close supervision by your doctor
- other medicines to reduce your blood pressure
- oral agents for diabetes or insulin
- resins used for high cholesterol, such as colestyramine
- ‘pressor amines’ such as adrenaline or other drugs from the same group
- steroids
- sleeping tablets
- opioid medicines such as morphine
- if you are taking potassium supplements, potassium-containing salt substitutes, potassium-sparing medicines, or other medicines that may increase serum potassium
- medicines which relax your muscles
- if you are taking calcium salts

Special precautionary measures (e.g. blood tests) may be appropriate if you take other diuretics (“water tablets”), some laxatives, medicines for the treatment of gout, medicines to control heart rhythm or for diabetes (oral agents or insulins).

Please also inform your doctor you are taking this medicine if you will be undergoing a radiographic procedure and will be given iodine contrast media.

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

Asomex D should not be used for essential hypertension in pregnant women except in rare situations where no other treatment could be used.

Breast-feeding

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

Asomex D is not recommended during breast-feeding.

Driving and using machines

When you begin treatment with this medication, you should not perform tasks which may require special attention (for example, driving an automobile or operating dangerous machinery) until you know how you tolerate your medicine.

3. HOW TO TAKE ASOMEX D

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 one tablet to be taken once daily.

You should take this medicine at the same time each day with a drink of water. Do not take this medicine with grapefruit juice.

If you take more Asomex D 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 D tablets.

Excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may develop up to 24-48 hours after intake.

If you stop taking Asomex D

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 D 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
- any type of pain in the head
- breathlessness

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, sleep disorders
- Trembling, taste abnormalities, fainting
- Numbness or tingling sensation in your limbs; loss of pain sensation
- ringing in the ears
- Low blood pressure, inflammation of blood vessels, which is often associated with a skin rash or bruising
- 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
- anaemia, red or brownish spots on the skin (sometimes especially on the feet, legs, arms and buttocks, with joint pain, swelling of the hands and feet and stomach pain), bruising, reduction in white blood cells, clotting problems, reduced number of platelets which may result in unusual bruising or easy bleeding
- loss of appetite, increased uric acid levels or frank gout, increased blood sugar levels, abnormal blood electrolyte levels
- blurred vision, seeing things in yellow
- pneumonia, water on the lungs (which causes difficulty breathing)
- constipation, stomach irritation, stomach spasms, inflammation of a salivary gland,

- inflammation of the pancreas
- sensitivity to light, itching, severe skin reaction (toxic epidermal necrolysis)
- sugar in urine, abnormal kidney function including inflammation of the kidneys
- fever

Rare: may affect up to 1 in 1000 people

- Confusion
- severe allergic reaction

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

- 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 and eyes (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
- acute respiratory distress (signs include severe shortness of breath, fever, weakness and confusion)

Not known: frequency cannot be estimated from the available data

- skin disease (cutaneous lupus erythematosus)
- skin and lip cancer (non-melanoma skin cancer)
- Trembling, rigid posture, mask-like face, slow movements and a shuffling, unbalanced Walk
- decrease in vision or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute angle-closure glaucoma).

During post-marketing, the following adverse events were reported with s-amlodipine of Emcure:

Peripheral edema, palpitations, increased blood glucose, gastrointestinal hemorrhage, pollakiuria, headache, fall, somnolence, erectile dysfunction, tinnitus, tongue discomfort, depression, hypertension, dysphagia, insomnia, decreased weight, generalized anxiety disorder, cough, feeling abnormal, tooth infection, upper abdominal pain, dizziness, skull fracture, pyrexia, diarrhea.

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 D

Store in a dry and dark place, below 30° C.

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

What Asomex D contains

The active substance is S (-) Amlodipine Besilate [eq. to S (-) Amlodipine 2.5mg]

The other ingredients are :

1. Hydrochlorothiazide
2. Microcrystalline Cellulose
3. Pregelatinised Starch
4. Lake FD&C Yellow No. 6 (Sunset Yellow)
5. Colloidal Silicon Dioxide
6. Sodium Starch Glycolate
7. Talc
8. Magnesium Stearate

What Asomex D looks like and contents of the pack

3X10's Blister Tablets

Asomex-D tablets are packed in blister pack [Amber colored PVDC coated PVC film/Aluminium foil] of 10 tablets.

The proposed pack size for Asomex-D tablets is blister pack of 3 x 10 tablets in a carton along with pack insert.

Marketing Authorization Holder and Manufacturer

Marketing Authorisation Holder

Emcure Pharmaceuticals Limited, India.

Manufacturer

Emcure Pharmaceuticals Limited, India.