125.00 mm

285.00 mm

Package leaflet: Information for the patient

NATRILAM®

1.5 mg / 5 mg sustained-release tablets
1.5 mg / 10 mg sustained-release tablets
Indapamide / Amlodipine

نیٹریلیَم

۱.۵ ایم جی گرام/۵ ایم جی گرام سسٹینڈ ریلیز گولیاں
۱.۵ ایم جی گرام/۱۰ ایم جی گرام سسٹینڈ ریلیز گولیاں
انڈاپامائیڈ/ایملوڈیپین

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

What is in this leaflet

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

1. What Natrilam is and what it is used for

Natrilam is prescribed as substitution treatment for high blood pressure (hypertension) in patients already taking indapamide and amlodipine from separate tablets in the same strength.

Natrilam is a combination of two active ingredients, indapamide and amlodipine.
Indapamide is a diuretic. Diuretics increase the amount of urine produced by the kidneys. However, indapamide is different from other diuretics, as it only causes a slight increase in the amount of urine produced. Amlodipine is a calcium antagonist (which belongs to a class of medicines called dihydropyridines) and it works by relaxing blood vessels, so that blood passes through them more easily. Each of the active ingredients reduces blood pressure.

2. What you need to know before you take Natrilam

Do not take Natrilam
- if you are allergic to indapamide or any other sulfonamide (class of medicinal product for the treatment of hypertension), or to amlodipine or any other calcium antagonist (class of medicinal product for the treatment of hypertension) or to any of the other ingredients of this medicine (listed in section 6). 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,
- if you have severe kidney disease,
- if you have severe liver disease or suffer from a condition called hepatic encephalopathy (disease of the brain caused by liver illness),
- if you have low potassium levels in your blood,

Warnings and precautions
Talk to your doctor or pharmacist before taking Natrilam.

You should inform your doctor if you have or have had any of the following conditions:
- recent heart attack,
- if you have heart failure, any heart rhythm problems, if you have coronary artery disease (heart disease caused by poor blood flow in the blood vessels of the heart),
- if you have problems with your kidneys,
- 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 Natrilam. 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 muscle disorders including muscle pain, tenderness, weakness or cramps,
- severe increase in blood pressure (hypertensive crisis),
- you are elderly and your dose needs to be increased,
- if you take other medicines,
- if you are malnourished,
- if you have liver problems,
- if you have diabetes,
- if you suffer from gout,
- if you need to have a test to check how well your parathyroid gland is working,
- if you have had photosensitivity reactions.

Your doctor may prescribe you blood tests to check for low sodium or potassium levels or high calcium levels.
If you think any of these situations may apply to you or you have any questions or doubts about taking your medicine, you should consult your doctor or pharmacist.
Athletes should be aware that Natrilam contains an active ingredient (indapamide) which may give a positive reaction in drug tests.

Children and adolescents
Natrilam should not be given to children and adolescents.

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

You should not take Natrilam:
- with lithium (used to treat mental disorders such as mania, manic depressive illness and recurrent depression) due to the risk of increased levels of lithium in the blood,
- with dantrolene (infusion for severe body temperature abnormalities).

Make sure to tell your doctor if you are taking any of the following medicines, as special care may be required:
- other medicines for treating high blood pressure,
- medicines used for heart rhythm problems (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, ibutilide, dofetilide, bretylium),
- medicines used to treat mental disorders such as depression, anxiety, schizophrenia... (e.g. tricyclic antidepressants, antipsychotic drugs, neuroleptics (such as amisulpride, sulpiride, sultopride, tiapride, haloperidol, droperidol)),
- bepridil (used to treat angina pectoris, a condition causing chest pain),
- cisapride, diphemanil(used to treat gastro-intestinal problems),
- vincamine IV (used to treat symptomatic cognitive disorders in elderly including memory loss),
- halofantrine (antiparasitic drug used to treat certain types of malaria),
- pentamidine (used to treat certain types of pneumonia),
- antihistamines used to treat allergic reactions, such as hay fever (e.g mizolastine, astemizole, terfenadine),
- non-steroidal anti-inflammatory drugs for pain relief (e.g. ibuprofen) or high doses of acetylsalicylic acid,
- angiotensin converting enzyme (ACE) inhibitors (used to treat high blood pressure and heart failure),
- oral corticosteroids used to treat various conditions including severe asthma and rheumatoid arthritis,
- digitalis preparations (for the treatment of heart problems),
- stimulant laxatives,
- baclofen (to treat muscle stiffness occurring in diseases such as multiple sclerosis),
- potassium-sparing diuretics (amiloride, spironolactone, triamterene),
- metformin (to treat diabetes),
- iodinated contrast media (used for tests involving X-rays),
- calcium tablets or other calcium supplements,
- immunosuppressants (medicines used to control your body's immune response) for the treatment of auto-immune disorders or following transplant surgery (e.g. ciclosporin, tacrolimus),
- sirolimus, temsirolimus, everolimus and other drugs belonging to the class of so-called mTOR inhibitors (medicines used to alter the way your immune system works),
- tetracosactide (to treat Crohn's disease),
- antifungal medicines (e.g ketoconazole, itraconazole, amphotericin B by injection),
- ritonavir, indinavir, nelfinavir (so called protease inhibitors used to treat HIV),
- antibiotics used to treat bacterial infections (e.g rifampicin, erythromycin by injection, clarithromycin, sparfloxacin, moxifloxacin),
- hypericum perforatum (St. John's Wort),
- verapamil, diltiazem (heart medicines),
- simvastatin (cholesterol lowering medicine),
- allopurinol (to treat gout),
- methadone (used to treat addiction).

Natrilam with food and drink
Grapefruit juice and grapefruit should not be consumed by people who are taking Natrilam. This is because grapefruit and grapefruit juice can 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 Natrilam.

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.
This medicine is not recommended during pregnancy. When a pregnancy is planned or confirmed, the switch to an alternative treatment should be initiated as soon as possible.

Natrilam is not recommended if you are breast-feeding. Tell your doctor immediately if you are breast-feeding or about to start breast-feeding.

Driving and using machines
Natrilam 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. If this occurs, you should refrain from driving and other activities requiring alertness.

Natrilam contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Natrilam contains sodium
Natrilam contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Natrilam

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

125mm

285mm

Package leaflet: Information for the patient

The recommended dose is one tablet once a day, preferably in the morning.
The tablet should be swallowed whole with water and should not be chewed.

If you take more Natrilam than you should
Taking too many tablets may cause your blood pressure to become low or even dangerously low. You may feel dizzy, drowsy, lightheaded, faint or weak. You may experience nausea, vomiting, cramps, confusion and changes in the amount of urine produced by the kidneys. If a blood pressure drop is severe enough shock can occur. Your skin could feel cool and clammy and you could lose consciousness.
Excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may develop up to 24-48 hours after intake.
Seek immediate medical attention if you take too many Natrilam tablets.

If you forget to take Natrilam
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 forgotten dose.

If you stop taking Natrilam
As the treatment for high blood pressure is usually life-long, you should discuss with your doctor before stopping this medicinal product.

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.

Stop taking the medicinal product and visit your doctor immediately if you experience any of the following side effects that can be serious:
- swelling of eyelids, face or lips (very rare, may affect up to 1 in 10,000 people),
- swelling of the tongue and throat which causes great difficulty breathing (very rare, may affect up to 1 in 10,000 people),
- 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, Toxic Epidermal Necrolysis) or other allergic reactions (very rare, may affect up to 1 in 10,000 people),
- heart attack (very rare, may affect up to 1 in 10,000 people),
- abnormal heartbeat (uncommon, may affect up to 1 in 100 people),
- life-threatening irregular beat (torsade de pointes) (frequency not known),
- inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell (very rare, may affect up to 1 in 10,000 people),
- muscle weakness, cramps, tenderness or pain and particularly, if at the same time, you feel unwell or have a high temperature it may be caused by an abnormal muscle breakdown (Not known).

In decreasing order of frequency, other side effects can include:

Very common: may affect more than 1 in 10 people
- oedema (fluid retention).

Common: may affect up to 1 in 10 people
- headache, dizziness, sleepiness (especially at the beginning of treatment),
- visual impairment, double vision,
- palpitations (awareness of your heartbeat), flushing,
- shortness of breath,
- abdominal pain, feeling sick (nausea), change of bowel habit, diarrhoea, constipation, indigestion,
- ankle swelling, tiredness, weakness, muscle spasms,
- low potassium in the blood, which may cause muscle weakness,
- skin rashes.

Uncommon: may affect up to 1 in 100 people
- mood altered, anxiety, depression, sleeplessness,
- trembling,
- taste abnormalities,
- numbness or tingling sensation in your limbs, loss of pain sensation,
- ringing in the ears,
- low blood pressure,
- low sodium in the blood that may lead to dehydration and low blood pressure,
- fainting,
- 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 discolouration, hives,
- disorder in passing urine, increased need to urinate at night, increased number of times of passing urine,
- impotence (inability to obtain or maintain an erection); discomfort or enlargement of the breasts in men,
- pain, feeling unwell,
- joint or muscle pain, back pain,
- weight increased or decreased.

Rare: may affect up to 1 in 1,000 people
- confusional state,
- feeling of dizziness,
- low chloride in the blood,
- low magnesium in the blood .

Very rare: may affect up to 1 in 10,000 people
- changes in blood cells, such as thrombocytopenia (decrease in the number of platelets which causes easy bruising and nasal bleeding), leucopenia (decrease of white blood cells which may cause unexplained fever, soreness of the throat or other flu-like symptoms – if this occurs, contact your doctor) and anaemia (decrease in red blood cells),
- excess sugar in blood (hyperglycaemia),
- increase of calcium in blood,
- a disorder of the nerves which can cause weakness, tingling or numbness,
- swelling of the gums,
- abdominal bloating (gastritis),
- hepatic function abnormal, inflammation of the liver (hepatitis), yellowing of the skin (jaundice), liver enzyme increase which may have an effect on some medical tests ; in cases of liver failure, there is a possibility of getting hepatic encephalopathy (disease in the brain caused by liver illness),
- kidney disease,
- increased muscle tension,
- inflammation of blood vessels, often with skin rash,
- sensitivity to light.

Not known (frequency cannot be estimated from the available data):
- changes may occur in your laboratory parameters and your doctor may need to give you blood tests to check your condition. The following changes in laboratory parameters may occur:
  . increase in uric acid, a substance which may cause or worsen gout (painful joint(s) especially in the feet),
  . increase in blood glucose levels in diabetic patients,
- abnormal ECG tracing,
- short sightedness (myopia),
- vision blurred,
- 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),
- trembling, rigid posture, mask-like face, slow movements and a shuffling, unbalanced walk.

If you suffer from systemic lupus erythematosus (a type of collagen disease), this might get worse.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.
You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Natrilam

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

Do not use this medicine after the expiry date which is stated on the carton and the blister or container. The expiry date refers to the last day of that month.

Store below 30°C.

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 Natrilam contains

- The active substances are indapamide and amlodipine.
  One tablet of Natrilam 1.5 mg / 5 mg contains 1.5 mg indapamide and 6.935 mg amlodipine besilate equivalent to 5 mg amlodipine.
  One tablet of Natrilam 1.5 mg / 10 mg contains 1.5 mg indapamide and 13.87 mg amlodipine besilate equivalent to 10 mg amlodipine.
- The other ingredients are:
  - Tablet core for Natrilam 1.5mg / 5mg and 1.5mg / 10mg: lactose monohydrate, hypromellose (E464), magnesium stearate (E572), povidone (E1201), silica colloidal anhydrous, calcium hydrogen phosphate dihydrate, cellulose microcrystalline (E460), croscarmellose sodium (E468), pregelatinised maize starch,
  - Tablet film - coating for Natrilam 1.5mg / 5mg: glycerol (E422), hypromellose (E464), macrogol 6000, magnesium stearate (E572), titanium dioxide (E171),
  - Tablet film - coating for Natrilam 1.5mg / 10mg: glycerol (E422), hypromellose (E464), iron oxide red (E172), macrogol 6000, magnesium stearate (E572), titanium dioxide (E171).

Contains lactose monohydrate.

What Natrilam looks like and contents of the pack
Natrilam 1.5 mg / 5 mg tablets are white, round, film-coated, sustained-release tablets of 9 mm diameter engraved with  on one face.
Natrilam 1.5 mg / 10 mg tablets are pink, round, film-coated, sustained-release tablets of 9 mm diameter engraved with  on one face.

The tablets are available in blisters of 30 tablets .

Marketing Authorisation Holder and Manufacturer
Servier Research and Pharmaceuticals [Pakistan] (Pvt)Ltd
9-KM Sheikhupura Road Lahore Pakistan.
04235879500-6

Date of Revision of Text: April 2025

04147
Version-07

SERVIER

Manufactured by :
Servier Research & Pharmaceuticals [Pakistan] (Pvt.) Ltd.
9-Km Sheikhupura Road, Lahore - Pakistan
Under Licence **Les Laboratoires Servier** - France