125.00 mm

285.00 mm

Package leaflet: Information for the user

NATRILIX® SR

INDAPAMIDE

NATRILIX SR 1.5 mg prolonged-release film-coated tablets

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 NATRILIX SR 1.5 mg is and what it is used for

NATRILIX SR 1.5 mg is a prolonged-release film-coated tablet containing Indapamide as active ingredient.
Indapamide is a diuretic. Most 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.

This medicine is intended to reduce high blood pressure (hypertension) in adults.

2. What you need to know before you take NATRILIX SR 1.5 mg

Do not take NATRILIX SR 1.5 mg:
- If you are allergic to Indapamide or any other sulphonamide or to any of the other ingredients of this medicine (listed in section 6),
- if you have severe kidney disease,
- If you have severe liver disease or suffer from a condition called hepatic encephalopathy (degenerative disease of the brain),
- If you have low potassium levels in your blood.

Warnings and precautions:
Talk to your doctor or pharmacist before taking NATRILIX SR 1.5 mg:
- If you have liver problems,
- If you have diabetes,
- If you suffer from gout,
- If you have any heart rhythm problems or 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 NATRILIX SR 1.5 mg. 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,
- If you need to have a test to check how well your parathyroid gland is working.

You should tell your doctor if you had photosensitivity reactions.
Your doctor may give 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 this medicine contains an active ingredient, which may give a positive reaction in doping tests.

Other medicines and NATRILIX SR 1.5 mg:
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
You should not take NATRILIX SR 1.5 mg with lithium (used to treat depression) due to the risk of increased levels of lithium in the blood.
Make sure to tell your doctor if you are taking any of the following medicines, as special care may be required:
- medicines used for heart rhythm problems (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, ibutilide, dofetilide, digitalis, 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),
- antibiotics used to treat bacterial infections (e.g sparfloxacin, moxifloxacin, erythromycin by injection),
- vincamine by injection (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),
- amphotericin B by injection (anti-fungal medicines),
- oral corticosteroids used to treat various conditions including severe asthma and rheumatoid arthritis,
- stimulant laxatives,
- baclofen (to treat muscle stiffness occurring in diseases such as multiple sclerosis),
- allopurinol (for the treatment of gout),
- potassium-sparing diuretics (e.g amiloride, spironolactone, triamterene),
- metformin (to treat diabetes),
- iodinated contrast media (used for tests involving X-rays),
- calcium tablets or other calcium supplements,
- ciclosporin, tacrolimus or other medicines to depress the immune system after organ transplantation, to treat autoimmune diseases, or severe rheumatic or dermatological diseases,
- tetracosactide (to treat Crohn's disease),
- methadone (used to treat addiction),

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. Please tell your doctor if you are pregnant or wish to become pregnant.
The active ingredient is excreted in milk. Breastfeeding is not recommended if you are taking this medicine.

Driving and using machines:
This medicine can cause side effects due to lowering of the blood pressure such as dizziness or tiredness (see section 4). These side effects are more likely to occur after initiation of the treatment and after dose increases. If this occurs, you should refrain from driving and other activities requiring alertness. However, under good control, these side effects are unlikely to occur.

NATRILIX SR 1.5mg contains lactose monohydrate.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take NATRILIX SR 1.5 mg

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
The recommended dose is one tablet each day, preferably in the morning.
The tablets can be taken irrespective of meals. They should be swallowed whole with water. Do not crush or chew them.
Treatment for high blood pressure is usually life-long.

If you take more NATRILIX SR 1.5 mg than you should:
If you have taken too many tablets, contact your doctor or pharmacist immediately.
A very large dose of NATRILIX SR 1.5 mg could cause nausea, vomiting, low blood pressure, cramps, dizziness, drowsiness, confusion and changes in the amount of urine produced by the kidneys.

If you forget to take NATRILIX SR 1.5 mg:
If you forget to take a dose of your medicine, take the next dose at the usual time.
Do not take a double dose to make up for a forgotten dose.

If you stop taking NATRILIX SR 1.5 mg:
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.

125.00 mm

285.00 mm

Stop taking the medicinal product and see a doctor immediately, if you experience any of the following side effects that can be serious:
- Angioedema and/or urticaria. Angioedema is characterised by swelling of the skin of extremities or face, swelling of the lips or tongue, swelling of the mucous membranes of the throat or airways resulting in shortness of breath or difficulty of swallowing. If this occurs, contact your doctor immediately. (Very rare) (may affect up to 1 in 10,000 people)
- Severe skin reactions including intense skin rash, 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, (Very rare) (may affect up to 1 in 10,000 people)
- Life-threatening irregular beat. (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)
- Disease of the brain caused by liver illness (Hepatic encephalopathy) (Not known)
- Inflammation of the liver (Hepatitis) (Not known)
- 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:
Common (may affect up to 1 in 10 people):
- Red raised skin rash
- Allergic reactions, mainly dermatological, in subjects with a predisposition to allergic and asthmatic reactions.
- Low potassium in the blood

Uncommon (may affect up to 1 in 100 people):
- Vomiting,
- Red pinpoints on skin (Purpura)
- Low sodium in the blood that may lead to dehydration and low blood pressure,
- Impotence (inability to obtain or maintain an erection).

Rare (may affect up to 1 in 1000 people):
- Feeling of tiredness, headache, pins and needles (paresthesia), vertigo;
- Gastro-intestinal disorders (such as nausea, constipation), dry mouth;
- 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);
- High level of calcium in blood;
- Heart rhythm irregularities, low blood pressure;
- Kidney disease;
- Abnormal hepatic function.

Not known (frequency cannot be estimated from the available data):
- Fainting
- If you suffer from systemic lupus erythematous (a type of collagen disease), this might get worse.
- Cases of photosensitivity reactions (change in skin appearance) after exposure to the sun or artificial UVA have also been reported.
- Short sightedness (myopia).
- Blurred vision.
- Visual impairment.
- 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).
- Changes may occur in your laboratory parameters (blood tests) 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,
  . increased levels of liver enzymes.
- Abnormal ECG heart tracing

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist. This includes any possible side effects not listed in this leaflet.
You can also report side effects directly to Drug Regulatory Authority of Pakistan www.dra.org.pk or to company website www.servierpakistan.com . By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store NATRILIX SR 1.5 mg

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 blister. 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 to protect the environment.

6. Contents of the pack and other information

What NATRILIX SR 1.5 mg contains:
The active substance is Indapamide. Each tablet contains 1.5 mg of Indapamide.
The other ingredients are:
- Tablet core: anhydrous colloidal silica (E551), hypromellose (E464), lactose monohydrate, magnesium stearate (E470B), povidone
- Film-coating: glycerol (E422), hypromellose (E464), macrogol 6000, magnesium stearate (E470B), titanium dioxide (E171).

What NATRILIX SR 1.5 mg looks like and contents of the pack:
This medicine is a white, round prolonged-release film-coated tablet.
The tablets are available in blisters of 30 tablets packed in a cardboard box.

Marketing Authorisation Holder and manufacturer
Servier Research and Pharmaceuticals Pakistan (Pvt)Ltd
Plant
9KM Sheikuhupura Road Lahore Pakistan
04235879500-6

Date of Revision of Text: March 2022

04036
Version-05

SERVIER

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