

NATRILIX SR 1.5 mg

Indapamide 1.5mg

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What Natrilix SR 1.5mg is used for

This medicine is intended to reduce high blood pressure (hypertension). It is a sustained-release film-coated tablet containing indapamide as active ingredient.

How Natrilix SR 1.5mg works

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. In addition, indapamide widens blood vessels so that blood passes through more easily. This helps to lower blood pressure.

Before you use Natrilix SR 1.5mg

- When you must not use it

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 Product Description),
- 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.

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.

- Before you start to use it

Warnings and precautions

Talk to your doctor or pharmacist before taking Natrilix SR 1.5mg :

- 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 anti-doping tests.

- Taking other medicines

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 (to treat 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).

How to use Natrilix SR 1.5mg

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

- When to use it

Take tablet preferably in the morning.

- How much to use

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.

- How long to use it

Treatment for high blood pressure is usually life-long.

Continue taking Natrilix SR 1.5 mg for as long as your doctor recommends.

- If you forget to use it

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 the forgotten dose.

- If you use too much (overdose)

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

While you are using Natrilix SR 1.5mg

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Natrilix SR 1.5mg.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

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

- Things to be careful of

Driving and using machines

This medicine can cause side effects due to lowering of the blood pressure such as dizziness or tiredness (see section Possible side effects). 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.

Possible side effects

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

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 pinpoint spots 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 erythematosus (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.
- Choroidal effusion (an abnormal building of liquid in your eye that may result in vision changes);
- Acute myopia (sudden nearsightedness or blurred vision);
- Acute angle-closure glaucoma (a rapid increased pressure in your eyes, eye pain). If left untreated, it may lead to permanent vision loss.

- 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:

- low potassium in the blood,
- low sodium in the blood that may lead to dehydration and low blood pressure,
- 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,
- increase of calcium in blood.
- elevation of liver enzyme levels.
- Abnormal electrocardiogram heart tracing

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Natrilix SR 1.5 mg

Storage

Keep out of the reach and sight 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

Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

Product description

- *What it looks like:*

This medicine is a white, round sustained-release film-coated tablet. The tablets are available in a box of 30 tablets.

- *Ingredients*

- Active substance:

The active substance is indapamide. Each tablet contains 1.5 mg of indapamide.

- Inactive ingredients:

In the tablet core: anhydrous colloidal silica (E551), hypromellose (E464), lactose monohydrate, magnesium stearate (E470B), povidone.

In the film-coating: glycerol (E422), hypromellose (E464), macrogol 6000, magnesium stearate (E470B), titanium dioxide (E171).

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