NATRILIX SR 1.5 mg

Indapamide 1.5mg

What is in this leaflet

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.

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 Natrilix SR 1.5 mg,
- 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 as the liver is no longer able to remove toxin in the blood),
- if you have low potassium levels in your blood.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

This medicine is not recommended during pregnancy. When a pregnancy is planned or confirmed, switching 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 advisable if you are taking this medicine.

- *Before you start to use it*

Take special care with 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 need to have a test to check your parathyroid gland.

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 Natrilix SR 1.5 mg contains an active ingredient, which may give a positive reaction in anti-doping control tests.

- *Taking other medicines*

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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),
- medicines used to treat mental disorders such as depression, anxiety, schizophrenia (e.g. tricyclic antidepressants, antipsychotic drugs, neuroleptics),
- bepridil (used to treat angina pectoris, a condition causing chest pain),
- cisapride, diphemanil (used to treat gastro-intestinal problems),
- sparfloxacin, moxifloxacin (antibiotics used to treat infections),
- halofantrine (antiparasitic drug used to treat certain types of malaria),

- pentamidine (used to treat certain types of pneumonia),
- mizolastine (used to treat allergic reactions, such as hay fever),
- 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,
- 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,
- 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).

How to use Natrilix SR 1.5mg

- *How much to use*

One tablet each day, preferably in the morning.

- *When to use it*

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.

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 phamacists 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.

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

- *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. 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.

Important information about some of the ingredients of Natrilix SR 1.5mg

This medicine contains lactose monohydrate.

Side effects

Like all medicines, Natrilix SR 1.5 mg, sustained-release film-coated tablet can cause side effects, although not everybody gets them.

These can include:

- Common (<1/10 , >1/100): low potassium in the blood, which may cause muscle weakness.
- Uncommon (< 1/100, >1/1000): vomiting, allergic reactions, mainly dermatological, such as skin rashes, purpura (red pinpoints on skin) in subjects with a predisposition to allergic and asthmatic reactions.
- Rare (< 1/1000, >1/10,000):
  - Feeling of tiredness, dizziness, headache, pins and needles (paresthesia);

  - Gastro-intestinal disorders (such as nausea, constipation), dry mouth;
- Very rarely (< 1/10,000):
  - Heart rhythm irregularities, low blood pressure;
  - Kidney disease;
  - Pancreatitis (inflammation of the pancreas which causes upper abdominal pain), abnormal liver function;
  - 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 caused unexplained fever, soreness of the throat or other flu-like symptoms – if this occurs, contact your doctor) and anaemia (decrease in red blood cells);
  - Angioedema and/or urticaria, severe skin manifestations. 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.

- Not known (cannot be estimated from the available data):

- Syncope
- In cases of liver failure, there is a possibility of getting hepatic encephalopathy (degenerative disease of the brain as the liver is no longer able to remove toxin in the blood);
- 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:
  - 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 tracing
- Life-threatening irregular heart beat (torsades de pointe).
- 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.
- Hepatitis

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 calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

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*

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

- *What it looks like*:

White, round prolonged-release film-coated tablet. Boxes of 30 tablets.

- *Ingredients*

  - Active substance:

  Indapamide ……..……1.5 mg

  - 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).

- *MAL number:*
MAL19973570A

Manufacturer
Les Laboratoires Servier Industrie
905 route de Saran
45520 Gidy
France

Product Registration Holder
Servier Malaysia Sdn Bhd
1301 Level 13, Uptown 2
No 2 Jalan SS 21/37,
Damansara Uptown
47400 Petaling Jaya
Selangor Darul Ehsan

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