NATRILIX® SR

INDAPAMIDE 1.5 mg

(Sustained-Release Film-Coated Tablet)

Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, if you are in doubt, please ask your doctor or your pharmacist for further information.
- This medicine has been prescribed for you personally. 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 get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT NATRILIX SR, sustained-release film-coated tablets IS AND WHAT IT IS USED FOR?

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

2. NECESSARY INFORMATION BEFORE YOU TAKE NATRILIX SR, sustained-release film-coated tablets

Do not take NATRILIX SR, sustained-release film-coated tablets:
- if you are allergic to indapamide or any other sulphonamide or to any of the other ingredients of NATRILIX SR.
- 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.

Take special care with NATRILIX SR, sustained-release film-coated tablets:
- 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, contains an active ingredient, which may give a positive reaction in doping tests.
The use of this medicinal product is not recommended in patients with problems of galactose intolerance, lactase deficiency or glucose-galactose malabsorption (rare hereditary diseases).

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, 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).

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, 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 advisable 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.
Important information about some of the ingredients of NATRILIX SR, sustained-release film-coated tablet:
This medicine contains lactose monohydrate.

3. HOW TO TAKE NATRILIX SR, sustained-release film-coated tablet?

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, sustained-release film-coated tablet, then you should:
If you have taken too many tablets, contact your doctor or pharmacist immediately.
A very large dose of NATRILIX SR, 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, sustained-release film-coated tablet:
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 stop taking NATRILIX SR, sustained-release film-coated tablet:
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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, NATRILIX SR, sustained-release film-coated tablet can cause side effects, although not everybody gets them.
- 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;
  - Increased risk of dehydration in the elderly and in patients suffering from heart failure.
- Very rare (< 1/10,000):
  - Heart rhythm irregularities, low blood pressure;
  - Kidney disease;
  - Pancreatitis (inflammation of the pancreas which causes upper abdominal pain), abnormal liver function. In cases of liver failure, there is a possibility of getting hepatic encephalopathy (degenerative disease in the brain);
  - 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);
  - 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.
  - 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.

Not known (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:
  - 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).
- Hepatitis
- Malaise

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.

5. HOW TO STORE NATRILIX SR, SUSTAINED-RELEASE FILM-COATED TABLET?

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.
Protect from direct light, heat & moisture.

6. FURTHER INFORMATION

What NATRILIX SR, sustained-release film-coated tablet contains:

The active substance is:

Indapamide.....1.5 mg
for a sustained-release film-coated tablet

The other ingredients are:

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).

What NATRILIX SR, sustained-release film-coated tablet contains looks like and contents of the pack:
White, round prolonged-release film-coated tablet.
Boxes of 30 tablets.

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

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