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Package leaflet: Information for the patient

NATRILIX®

*INDAPAMIDE 2.5*mg

2.5 mg, film-coated tablet Indapamide hemihydrate

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® 2.5 mg, film-coated tablet IS AND WHAT IT IS USED FOR

Pharmacotherapeutic group
DIURETIC ANTIHYPERTENSIVE AGENT
(C: Cardiovascular system).

Therapeutic indications
This medicine is intended for the treatment of high blood pressure (hypertension).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE NATRILIX ® 2.5 mg, film coated tablet

List of information necessary before taking the medicinal product
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Contraindications
Do not take NATRILIX 2.5 mg, film-coated tablet:
- if you are allergic to indapamide or any other sulphonamide or to any of the other ingredients of NATRILIX 2.5 mg, film coated tablet (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.

Precautions for use; special warnings
Warnings and precautions for use:
Talk to your doctor or pharmacist before taking NATRILIX 2.5 mg, film-coated tablet:

- 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 how well your parathyroid gland is working.

You should tell your doctor if you have 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 other questions on the use of this medicine, you should consult your doctor or pharmacist.
Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Interactions with other medicinal products
Other medicines and NATRILIX 2.5 mg, film-coated tablet:
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
You should not take NATRILIX 2.5 mg, film-coated tablet 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, IV erythromycin (antibiotics used to treat infections),
- IV vincamine (used to treat symptomatic cognitive disorders in the elderly, including memory loss),
- 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),
- IV amphotericin B (anti-fungal drug),
- oral corticosteroids used to treat various conditions: 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).

Interactions with food and drink
Not applicable.

Interactions with herbal therapy products or alternative therapies
Not applicable.

Use during pregnancy and breast-feeding
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 breast milk. Breast-feeding is not advisable if you are taking this medicine.
Athletes
Athletes should be aware that this product contains an active ingredient which may give a positive reaction in doping tests.

Effects on the ability to drive and use machines
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.

List of excipients with a known effect
List of excipients with a known effect: lactose.

3. HOW TO TAKE NATRILIX 2.5 mg, film-coated tablet

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

Posology, Method and/or route(s) of administration, Frequency of administration and Duration of treatment
Dosage
One tablet each day.
ALWAYS STRICTLY FOLLOW YOUR DOCTOR'S PRESCRIPTION.

Method of administration
Oral route.
Frequency of administration
One dose every 24 hours, preferably in the morning given the medicine's diuretic effect in order to avoid having to get up in the night.
Duration of treatment
ACCORDING TO YOUR DOCTOR'S PRESCRIPTION.

Symptoms and instructions in case of overdose
If you take more NATRILIX 2.5 mg, film-coated tablet than you should:
If you have taken too many tablets, contact your doctor or pharmacist immediately.
A very large dose of NATRILIX 2.5 mg, film-coated tablet could cause nausea, vomiting, low blood pressure, cramps, dizziness, drowsiness, confusion and changes in the amount of urine produced by the kidneys.

Instructions in the event of omission of one or more doses
If you forget to take NATRILIX 2.5 mg, film-coated tablet:
If you forget to take NATRILIX 2.5 mg, film-coated tablet simply take your treatment as usual the next day.
Do not take a double dose to make up for a forgotten dose.

Risk of withdrawal syndrome
Not applicable.

4. POSSIBLE SIDE EFFECTS

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

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Stop taking the medicinal product and consult a doctor immediately if you experience any of the following side effects:

- angioedema and/or urticaria, severe skin reactions. Angioedema is characterised by swelling of the extremities or face, swelling of the lips or tongue, swelling of the mucous membranes of the throat or airways resulting in difficulty breathing or 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 heartbeat (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),
- brain disease caused by a liver disease (hepatic encephalopathy) (frequency not known),
- inflammation of the liver (hepatitis) (frequency not known).

By decreasing order of frequency, the other side effects may include:

Common (may affect up to 1 in 10 people):
raised skin rashes,

- allergic reactions, mainly dermatological, in subjects predisposed to allergic or asthmatic reactions.

Uncommon (less than 1 patient per 10,000):

- vomiting,
- red pinpoints on skin (purpura).

Rare (may affect up to 1 in 1,000 people) :

- feeling of tiredness, headache, pins and needles (paraesthesia), dizziness,
- gastro-intestinal disorders (such as nausea, constipation), dry mouth.

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 bruising, contusions and nasal bleeding), leucopenia (decrease in 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),
- increase of calcium in the blood,
- heart rhythm irregularities, low blood pressure,
- kidney disease,
- abnormal liver function.

Not known:

- 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 been reported,
- shortsightedness (myopia),
- blurred vision,
- vision disorders,
- 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:
  - o reduced blood potassium levels,
  - o reduced blood sodium levels which may lead to dehydration and low blood pressure,
  - o increased uric acid levels which may cause or worsen gout (painful joint(s) especially in the feet),
  - o increased of calcium in blood
  - o increased blood glucose levels in diabetic patients,
  - o increased liver enzyme levels,

    abnormal ECG heart tracing.

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

5. HOW TO STORE NATRILIX ® 2.5 mg, film-coated tablet
Keep this medicine out of the sight and reach of children.

Expiry date
Do not use this medicine after the expiry date which is stated on the box after {EXP}. The expiry date refers to the last day of that month.

Storage conditions
Store below 25°C.

If necessary, warnings against certain visible signs of deterioration
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. FURTHER INFORMATION

Full list of active substances and excipients
What NATRILIX 2.5 mg, film-coated tablet contains

The active substance is:
Indapamide hemihydrate
For one film-coated tablet.
The other ingredients are:
Maize starch, lactose, magnesium stearate, talc, povidone.
Film-coating: white beeswax, titanium dioxide (E171), glycerol, sodium lauryl sulphate, methylhydroxypropylcellulose, polyethylene glycol 6000, magnesium stearate.

Pharmaceutical form and contents
What NATRILIX 2.5 mg, film-coated tablet looks like and contents of the pack
This medicine is presented in the form of film-coated tablets. Box of 30 tablets.

MARKETING AUTHORISATION HOLDER
HEAD OFFICE
SERVIER RESEARCH & PHARMACEUTICALS [PAKISTAN] (PVT) LTD
65 MAIN BOULEVARD GULBERG LAHORE PAKISTAN

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SERVIER RESEARCH & PHARMACEUTICALS [PAKISTAN] (PVT) LTD
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