

## PACKAGE LEAFLET: INFORMATION FOR THE USER

# **NATRILIX**<sup>®</sup> **SR** 1.5 mg

INDAPAMIDE Tablets

*prolonged-release tablets*

### **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, ask your doctor or pharmacist.
- This medicine has been prescribed for you. 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 is and what it is used for
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### **1. WHAT NATRILIX SR 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 the 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. BEFORE YOU TAKE NATRILIX SR**

#### **Do not take Natrilix SR:**

- 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 (liver problems which affect the brain and central nervous system),
- if you have low potassium levels in your blood.

#### **Take special care with Natrilix SR:**

- 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 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.

### **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 (used to treat reduced movement of the gullet and stomach),
- diphemanil (used to treat gastric problems such as ulcers, too much acid, overactive digestive system),
- 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 such as dizziness or tiredness due to lowering of the blood pressure (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:**

This medicine 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**

### **Instructions for proper use:**

One tablet each day, preferably in the morning. The tablets can be taken with or without food. 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 than 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 (feeling sick), 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:**

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:**

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 can cause side effects, although not everybody gets them.

These can include:

- *Commonly (less than 1 patient in 10 but more than 1 in 100):* low potassium in the blood, which may cause muscle weakness.
- *Uncommonly (less than 1 patient in 100 but more than 1 in 1000):* vomiting, allergic reactions, mainly dermatological, such as skin rashes, purpura (red pinpoint spots on skin) in subjects with a tendency to allergic and asthmatic reactions.
- *Rarely (less than 1 patient in 1000 but more than 1 in 10,000):*
  - Feeling of tiredness, dizziness, headache, pins and needles (paresthesia);
  - nausea (feeling sick), constipation, dry mouth;
  - Increased risk of dehydration in the elderly and in patients suffering from heart failure.
- *Very rarely (less than 1 patient in 10,000):*
  - Heart rhythm irregularities (causing palpitations, feeling of the heart pounding), low blood pressure;
  - Kidney disease (causing symptoms of tiredness, increased

- need to urinate, itchy skin, feeling sick, swollen extremities);
- Pancreatitis (inflammation of the pancreas which causes upper abdominal pain), abnormal liver function (with symptoms such as tiredness, loss of appetite, feeling or being sick, swollen extremities, yellow skin). In cases of liver failure, there is a possibility of getting hepatic encephalopathy (liver problems which affect the brain and central nervous system);
- Changes in blood cells, such as thrombocytopenia (decrease in the number of platelets which causes easy bruising 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);
- Angioedema and/or urticaria, severe skin manifestations. Angioedema is characterised by swelling of the skin around the eyes, lips, hands or feet. It may cause swelling of the throat, tongue or airways resulting in shortness of breath or difficulty in swallowing. If this occurs, contact your doctor immediately.

If you suffer from systemic lupus erythematosus (a disorder of the immune system leading to inflammation and damage to the joints, tendons and organs with symptoms including skin rashes, tiredness, loss of appetite, weight gain and joint pain), this might get worse. Cases of photosensitivity reactions (change in skin appearance) after exposure to the sun or artificial UVA have also been reported.

Some changes may occur in your blood and your doctor may need to give you blood tests to check your condition. The following changes in your blood test results 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.

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.

## 5. HOW TO STORE NATRILIX SR

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.

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.

## 6. FURTHER INFORMATION

### What Natrilix SR 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 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 10, 14, 15, 20, 30, 50, 60, 90 or 100 tablets packed in a cardboard box. Not all pack sizes may be marketed.

### Marketing Authorisation Holder and manufacturer

#### Marketing Authorisation Holder:



Les Laboratoires Servier  
22, rue Garnier  
92200 Neuilly-sur-Seine – France

#### Manufacturer:

Servier (Ireland) Industries Ltd  
Gorey Road  
Co. Wicklow – Arklow  
Ireland

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	FLUDEX RETARD 1.5 mg
Belgium	FLUDEX 1.5 mg
Cyprus	FLUDEX 1.5 mg
Czech Republic	TERTENSIF SR
Denmark	NATRILIX RETARD
Estonia	TERTENSIF SR
Finland	NATRILIX RETARD 1.5 mg
France	FLUDEX 1.5 mg
Germany	NATRILIX SR 1.5 mg
Greece	FLUDEX 1.5 mg
Hungary	PRETANIX
Ireland	NATRILIX SR
Italy	NATRILIX LP 1.5 mg
Latvia	TERTENSIF SR
Lithuania	TERTENSIF SR
Luxembourg	FLUDEX 1.5 mg
Malta	NATRILIX SR
Netherlands	FLUDEX SR 1.5 mg
Poland	INDAPAMIDE 1.5 mg SR SERVIER
Portugal	FLUDEX LP
Slovakia	TERTENSIF SR
Slovenia	TERTENSIF SR
Spain	TERTENSIF RETARD
United Kingdom	NATRILIX SR 1.5mg

**This leaflet was last approved in June 2008.**