

Napamide PR 1.5mg Prolonged Release Tablets

(Indapamide)

Read all of this leaflet carefully before you start taking 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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.**

In this leaflet:

- 1. What Napamide PR Tablets are and what they are used for**
- 2. Before you take Napamide PR Tablets**
- 3. How to take Napamide PR Tablets**
- 4. Possible side effects**
- 5. How to store Napamide PR Tablets**
- 6. Further information**

The name of this medicine is Napamide PR 1.5mg Prolonged Release Tablets. For convenience, this leaflet will call it Napamide PR Tablets.

1. What Napamide PR Tablets are and what they are used for

Napamide PR Tablets contain the active substance Indapamide. This belongs to a group of medicines called sulphonamides. These are often known as water tablets or diuretics.

This medicine lowers blood pressure (an antihypertensive) and is used in the treatment of raised blood pressure. Your doctor has diagnosed that you have raised blood pressure (hypertension) and has prescribed Napamide PR tablets to help improve your condition.

2. Before you take Napamide PR Tablets

Do not take Napamide PR Tablets:

- If you have had any unusual or allergic reaction (such as wheezing, swelling of the face or tongue, itching or skin rash) to Indapamide or sulphonamides in the past, or any of the other ingredients in Napamide PR Tablets (these are listed in Section 6, Further Information)
- If you suffer from severe liver disease, with or without involvement of the brain
- If you suffer from kidney failure
- If you have low blood potassium (your doctor will be able to tell you)

If any of these circumstances apply to you, tell your doctor immediately, as the tablets may not be suitable for you.

Napamide PR is not recommended for use in children and adolescents.

Take special care and tell your doctor or pharmacist before taking Napamide PR Tablets if:

- you suffer from mild/moderate liver disease, kidney disease or heart disease
- you suffer from diabetes or gout
- you have ever experienced photosensitivity reactions
- you have an imbalance of body chemicals (a blood test can determine this)

Athletes should be aware that Napamide PR Tablets contain indapamide which may give a positive reaction in drug tests.

Taking other medicines

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 Napamide with lithium (used to treat depression) due to the risk of increased levels of lithium in the blood.

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, diphermanil (used to treat gastrointestinal problems)
- sparfloxacin, moxifloxacin (antibiotics used to treat infections)
- halofantrine (antiparasitic drug used to treat certain types of malaria)
- pentamide (used to treat certain types of pneumonia)
- mizolastine (used to treat allergic reactions, such as hay fever)
- non-steroidal anti-inflammatory drugs (NSAIDs) 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 auto-immune diseases, or severe rheumatic or dermatological diseases
- tetracosactide (to treat Crohn's disease)

Taking with food and drink:

- Napamide PR Tablets should be taken whole with water first thing in the morning before breakfast.

Pregnancy and breast-feeding:

- You should not take Napamide PR Tablets if:
 - You are pregnant, planning to become pregnant or think you may be pregnant
 - You are breast-feeding

Driving and using machines:

- Your tablets do not affect alertness, but different reactions such as dizziness or weakness related to the lowering of blood pressure may occur in certain patients. As a result, the ability to drive or to operate machinery may be impaired. If you are affected, you should not drive until these reactions disappear. If you are not sure, ask your doctor or pharmacist.

Important information about some of the ingredients in Napamide PR Tablets:

This medicine contains a type of sugar called lactose monohydrate. If you have been told by your doctor that you are intolerant to some sugars and have to avoid them, contact your doctor before taking this medicine.

3. How to take your Napamide PR Tablets

- Always take Napamide PR Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
- The usual dose is one tablet taken first thing in the morning before breakfast. Swallow Napamide PR Tablets whole. **Do not crush, cut or chew the tablets.**
- Do not take more Napamide PR Tablets than your doctor recommended.
- It is important to keep taking your tablets until your doctor tells you to stop.

If you take more Napamide PR Tablets than you should

If you take too many tablets by accident or if a child has swallowed any of your tablets, contact your nearest hospital casualty department or your doctor immediately.

If you forget to take Napamide PR Tablets

If you forgot to take a tablet, take one as soon as you remember and carry on with the next dose as usual. Do not take an extra one to make up the missed dose.

If you stop taking Napamide PR Tablets

Do not stop taking the tablets without first checking with your doctor.

4. Possible Side Effects

Like all medicines, Napamide can cause side effects, although not everybody gets them. The following side effects are listed by frequency:

Common (more than 1 out of 100 persons and less than 1 out of 10 persons):

- low potassium in the blood, which may cause muscle weakness
- allergic reactions, mainly dermatological, such as skin rashes in subjects with a predisposition to allergic and asthmatic reactions

Uncommon (more than 1 out of 1,000 persons and less than 1 out of 100 persons):

- being sick (vomiting)
- purpura (red pinpoint spots on the skin)

Rare (more than 1 out of 10,000 persons and less than 1 out of 1,000 persons):

- dizziness; feeling tired (fatigue); headache; pins and needles (paresthesia)
- feeling sick (nausea); constipation; dry mouth

Very rare (less than 1 out of 10,000 persons):

- 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, sore throat and other flu-like symptoms (if this occurs, contact your doctor)), and anaemia (decrease in red blood cells)
- heart rhythm irregularities; low blood pressure
- pancreatitis (inflammation of the pancreas which causes upper abdominal pain)
- kidney disease
- abnormal liver function (In cases of liver failure, there is a possibility of getting hepatic encephalopathy (degenerative diseases in the brain))
- angioedema and/or urticaria (severe skin manifestations). Angioedema is characterized by swelling of the skin of the

extremities or face, lips or tongue, swelling of the mucous membranes of the throat or airways, resulting in shortness of breath or difficulty swallowing. If this occurs, contact your doctor immediately.

Frequency unknown (cannot be estimated from the available data):

- If you suffer from systemic lupus erythematosus (a type of collagen disease), this might get worse.
- Photo-sensitivity reactions (change in skin appearance when exposed to sunlight or artificial UVA)
- Some 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 (this can cause an increased risk of dehydration in the elderly and heart failure patients)
 - 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 joints, especially in the feet)
 - Increase in blood glucose levels in diabetic patients
 - Increase of calcium in the blood

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

5. How to store Napamide PR Tablets

This medicinal product does not require any special storage conditions.

- Keep all medicines out of the reach and sight of children.
- If your doctor decides to stop your treatment, return any tablets left over to the pharmacist. Only keep them if your doctor tells you.

Do not take Napamide PR Tablets if they are past the expiry date, which is clearly printed on the blister pack and the outer carton. If in doubt, check with your doctor or pharmacist.

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

Remember: This medicine is only for you. Never give this medicine to anyone else. It could harm them, even if their symptoms are the same as yours.

6. Further Information

What Napamide PR Tablets contain

The active substance is indapamide. Each prolonged release tablet contains 1.5mg indapamide.

The other ingredients are hypromellose, cellactose (containing lactose monohydrate and cellulose powder), colloidal anhydrous silica, magnesium stearate and opadry white Y-1-7000 (hypromellose, titanium dioxide (E171) and Macrogol 400).

What Napamide PR Tablets look like and contents of the pack

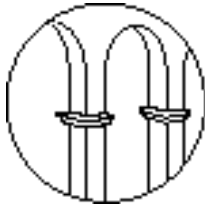
Napamide PR Tablets are white, round prolonged release tablets.

Napamide PR Tablets come in packs of 30 prolonged release tablets.

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Manufacturer: KRKA, d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto, Slovenia.

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| Title: | Napamide PR 1.5mg Niche IRE |
| Date of Origination: | 31/5/06 |
| Dimensions: | 148mm x 297mm |
| Pharma Code: | 739 |
| Component Code: | 219817 |
| EAN Number: | N/A |
| Software: | QuarkXpress 4.1 |
| Version Number: | 11 |
| Revision Date: | 5/10/2011 |
| Reason for Revision: | Renewal changes |
| Colours: | ■ Black |
| Regulatory Approval Date: | |
| Quality Approval Date: | |
| Submission Date: | |
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