1. **What Indapamide Tablets are and what they are used for**

This medicine is intended to reduce high blood pressure (hypertension). It is a 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. **What you need to know before you take Indapamide Tablets**

**Do not take Indapamide 2.5mg Tablets:**
- If you are allergic to indapamide or any of the other ingredients of this medicine (listed in section 6),
- 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.

**Warning and precautions**

Talk to your doctor or pharmacist before taking Indapamide Tablets.

**Take things into account if you have:**
- liver problems,
- if you have any heart rhythm problems or problems with your kidneys,
- if you have any diabetes (painful inflammation of the joints),
- diabetes,
- if you need to have a test to check how the 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.

**Other medicines and Indapamide Tablets**

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

You should not take Indapamide Tablets 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 gut and stomach),
- diphensal (used to treat gastro-intestinal problems such as ulcers, too much stomach acid (hyperacidity), stomach cancer),
- sparfloxacin, moxifloxacin (antibiotics used to treat infections),
- halofantrine (antiparasitic drug used to treat certain types of malaria),
- pentamidine (used to treat certain types of pneumoconiosis),
- mizolastine (used to treat allergic reactions, such as hay fever),
- non-steroidal anti-inflammatory drugs for pain (e.g. ibuprofen), or high doses of acetylsalicylic acid,
- angiotensin converting enzyme (ACE) inhibitors used to treat 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, triamterene),
- metformin (to treat diabetes),
- iodine or contrast media used (for tests involving X-rays),
- calcium tablets or other calcium preparations,
- 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).

**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.

**Indapamide Tablets contains Lactose**

This medicine contains lactose monohydrate. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

3. **How to take Indapamide Tablets**

Always take this medicine 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 each day, preferably in the morning. The tablets can be taken with or without food. They should be swallowed whole with water. Treatment for high blood pressure is usually lifelong.
Changes may occur in your blood and
cells, such as
- Increase of calcium in the blood;
- Kidney disease (causing symptoms of
  heart rhythm irregularities (causing
  increased risk of dehydration in the
  body);
- Nausea (feeling sick), constipation, dry
  mouth;
- Purpura (red pinpoints on skin);
- Vomiting;
- Allergic reactions, mainly dermatological,
  such as skin rashes in subjects with a
  predisposition to allergic and asthmatic
  reactions.

Common (less than 1 patient in 10 but
more than 1 in 100):
- Low potassium in the blood, which may
  cause muscle weakness;
- Allergic reactions, mainly dermatological,
  such as rashes in subjects with a
  predisposition to allergic and asthmatic
  reactions.

Uncommon (less than 1 patient in 100 but
more than 1 in 1000):
- Fatigue;
- Purpura (red pinpoints on skin).

Rare (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 older people and in patients suffering from heart failure.

Very rare (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);
- Increase of calcium in the blood;
- Palpitations (inflammation of the pericardium which causes upper abdominal pain), abnormal liver function (with symptoms such as tiredness, loss of appetite, feeling or being sick, swollen extremities, yellow skin);
- 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 around the eyes, lips, hands or feet. It may cause swelling of the throat, tongue or airways resulting in shortness of breath or difficulty of swallowing. If this occurs, contact your doctor immediately.

Not known (frequency cannot be estimated from the available data): 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 sodium in the blood which 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;
- increased levels of liver enzymes.

In cases of liver failure, there is a possibility of getting hepatic encephalopathy (liver problems which affect the brain and central nervous system);
- 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.
- Abnormal ECG heart tracing.
- Life-threatening irregular beat (Torsade de Pointes).

Hepatitis

Fainting

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme website www.mhra.gov.uk/yellowcard.

5. How to store Indapamide Tablets

Keep this medicine out of the sight and reach of children.

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

Do not store above 25°C. Store in the original package to protect from light.

Do not throw away any medicines via the wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Indapamide Tablets contain

Each tablet contains 2.5mg of Indapamide Ph. Eur. Indapamide Tablets also contain lactose, sodium starch glycollate, magnesium stearate.

What Indapamide Tablets look like and contents of the pack

Indapamide Tablets are round, white, bevelled edged tablet; embossed with I and 2.5 on one side, plain on the other side.

They are supplied in blister packs containing 20, 28, 30, 56, 60, 84 or 120 tablets.

Marketing Authorisation Holder
Niche Generics Limited, 1 The Cam Centre, Wilbury Way, Hitchin, Hertfordshire, SG4 0TW, United Kingdom

Manufacturers
Niche Generics Limited, Unit 5, 151 Baldylove Industrial Estate, Dublin 13, Ireland

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