

PACKAGE LEAFLET: INFORMATION FOR THE USER

**INDAPAMIDE 2.5MG TABLETS**

Indapamide

**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 Indapamide Tablets are and what they are used for
2. What you need to know before you take Indapamide Tablets
3. How to take Indapamide Tablets
4. Possible side effects
5. How to store Indapamide Tablets
6. Contents of the pack and other information

**1. WHAT INDAPAMIDE TABLETS ARE AND WHAT THEY ARE USED FOR**

The name of your medicine is Indapamide 2.5mg Tablets. They contain the active ingredient called Indapamide.

Indapamide Tablets belong to a group of medicines called anti-hypertensives. This medicine is used to treat high blood pressure and works by causing the kidneys to get rid of unneeded water and salt from the body into the urine. Indapamide is different from other medicines, 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 Tablets:**

- If you are allergic (hypersensitive) to Indapamide or any other sulfonamide or to any of the other ingredients of Indapamide Tablets. See section 6
- If you have or ever had severe kidney failure and/or liver problems
- 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 the blood

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Indapamide tablets

- If you have or ever had liver and/or kidney problems
- If you have or ever had heart rhythm problems
- If you have diabetes
- If you suffer from porphyria (abnormalities in the chemical steps that lead to the production of heme, a component of your blood and bone marrow)
- If you have gout (severe swelling and painful joints)
- If you have or ever had thyroid or parathyroid disease (which causes too low/high calcium levels in the bloodstream)
- If you have been told by your doctor that you have low levels of potassium in your blood (hypokalaemia)
- If you have photosensitivity reactions
- If you have been told by your doctor that you have low levels of sodium in the blood (hyponatraemia)

**Effects on laboratory tests**

Indapamide Tablets may lower potassium levels and your doctor may monitor this by means of blood tests. Blood calcium levels may need to be monitored in those patients suffering from overactivity of the parathyroid gland. Blood glucose levels may need to be monitored as this medicine may affect them.

Keep all appointments with your doctor and the laboratory. Your blood pressure should be checked regularly, and blood tests should be done occasionally.

**Athletes** – This drug contains the active ingredient that may give a positive reaction in the 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.

You should not take Indapamide if you are taking Lithium due to the risk of increased lithium levels in the body.

Examples of medicines that can affect Indapamide Tablets are:

- Carbenoxolone, which is used in the treatment of ulcers

- Diuretics or “water tablets”, such as bumetanide, furosemide, thiazides and xipamide
- Diuretics or “water tablets” such as amiloride, spironolactone and triamterene which increase the flow of urine without excessive loss of potassium
- Lithium, an antidepressant due to the risk of increased level of lithium in the blood
- Quinidine or cardioglycosides, such as digoxin, disopyramide, amiodarone and sotalol, ibutilide, dofetilide, digitalis which are used to treat abnormal heart beat
- Lidocaine, flecainide and mexiletine (to treat irregular heart beat)
- Intravenous erythromycin, an antibiotic
- Pentamidine (used in the treatment of protozoal infections)
- Prazosin, which is used to treat high blood pressure
- Antiepileptics such as oxcarbazepine
- Anti-psychotics such as pimozide and sertindole, which are used to treat some mental disorders
- Baclofen, which is a muscle relaxant (to treat muscle stiffness occurring in disease such as multiple sclerosis)
- ACE inhibitors (angiotensin converting enzyme inhibitors) such as e.g. captopril (to treat high blood pressure)
- NSAIDs (non-steroidal anti-inflammatory drugs) such as aspirin and ibuprofen (used in the management of arthritis)
- Amphotericin B (used to treat fungal infections)
- Tetracosactide (to assess adrenal gland function to treat Crohn's disease)
- Stimulant laxatives (to treat constipation)
- Metformin, which is used in the treatment of diabetes
- Anti-depressants and neuroleptics (to treat mental disorders)
- Calcium salts
- Ciclosporin and tacrolimus or other medicines to depress the immune system after organ transplantation, to treat autoimmune diseases, or severe rheumatic or dermatological diseases, which are used in patients who have had an organ transplant
- Tetracosactide or corticosteroids, which are used to reduce inflammation including severe asthma and rheumatoid arthritis
- Bepiridil (to treat angina pectoris, a condition causing chest pain)
- Cisapride (to treat reduced movement of the gullet and stomach)
- Dephemanil (used to treat gastro-intestinal problems such as ulcers, too much acid, overactive digestive system)
- Sparfloxacin, moxifloxacin (antibiotics used to treat infections)
- Halofantrine (to treat certain types of malaria)
- Pentamidine (used to treat certain types of pneumonia)
- Mizolastine (used to treat allergic reactions, such as hay fever)
- Iodinated contrast media (used for test involving X-rays)
- Calcium tablets or other calcium supplements

**Indapamide Tablets with food and drink**

Follow your doctor's directions. They may include a daily exercise program and a low-sodium or low-salt diet, potassium supplements, and increased amounts of potassium-rich foods (e.g., bananas, prunes, raisins and orange juice) in your diet.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription.

**Pregnancy, breast-feeding and fertility**

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 milk. Breast-feeding is not advisable if you are taking this medicine.

**Driving and using machines**

Indapamide Tablets may cause dizziness. Do not drive a car or operate machinery in such a case. Due to lowering of blood pressure (see section 4). These side effects are more likely to occur after initiation of the treatment and after dose increases. If this occur, you should refrain from driving and other activities requiring alertness. However, under good control, these side effects are unlikely to occur.

**Indapamide contains lactose monohydrate and sucrose**

This medicinal product contains Lactose and Sucrose. 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 INDAPAMIDE TABLETS**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The tablets can be taken with or without food.

**Dosage** - You should swallow the tablet whole with a glass of water.

**Adults and Elderly:** The recommended dose is one tablet (2.5mg) each day which should be swallowed with a glass of water. It is advised that the tablet be taken in the morning. Treatment for high blood pressure is usually life-long.

**Use in children:** Not recommended for children.

**If you take more Indapamide Tablets than you should**

If you take more Indapamide Tablets than you should, contact your doctor or nearest hospital emergency department immediately. Take the pack and remaining tablets with you. A very large dose of Indapamide 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 Indapamide Tablets**

If you forget to take a dose, take it as soon as you remember unless it is almost time for your next dose. Do not take a double dose to make up for a forgotten tablet.

**If you stop taking Indapamide Tablets**

Do not stop taking Indapamide Tablets without talking to your doctor, even if you feel better. It is important that you take the full course of Indapamide prescribed by your doctor. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4. POSSIBLE SIDE EFFECTS**

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

**Stop taking Indapamide Tablets and see a doctor immediately, if you experience any of the following side effects:**

- Angioedema and/or urticaria. Angioedema is characterised by swelling of the skin of extremities or face, swelling of the lips or tongue, swelling around the eyes, hands or feet. 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
- Severe skin reactions including intense skin rash, reddening of 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
- Life-threatening irregular beat
- Inflamed pancreas which may cause severe pain in the abdomen and back accompanied with feeling very unwell
- Disease of the brain caused by liver illness (Hepatic encephalopathy)
- Inflammation of liver (Hepatitis)
- Signs of inflammation of the liver, e.g. feeling sick, severe abdominal pain, being sick, tiredness and yellowing of the whites of the eyes and skin (jaundice)

**Common** (less than 1 patient in 10 but more than 1 in 100):

- Maculopapular rashes (red raised skin rash)
- Allergic reactions, mainly dermatological, such as skin rashes in subjects with a predispositions to allergic and asthmatic reactions

**Uncommon** (less than 1 patient in 100 but more than 1 in 1000):

- Vomiting (being sick)
- Purpura (red pinpoints on skin)

**Rare** (less than 1 patient in 1000 but more than 1 in 10,000):

- Feeling of tiredness, vertigo, fatigue, headache, pins and needles (paraesthesia)
- Gastrointestinal disorders such as nausea (feeling sick), constipation, dry mouth, dizziness
- Impotence (erectile dysfunction - characterized by the inability to develop or maintain an erection)
- Reversible acute myopia (problems in seeing long distance objects)
- Muscle cramps

**Very rare** (occurring in less than 1 in 10,000 patients):

- 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 throat or other flu-like symptoms - if this occurs, contact your doctor) and anaemia (decrease in red blood cells)

- High level of calcium in blood (Hypercalcaemia)
- Hypotension, heart rhythm irregularities (causing palpitations, feeling of the heart pounding)
- Diabetes mellitus
- Kidney disease (causing symptoms of tiredness, increased need to urinate, itchy skin, feeling sick, swollen extremities)
- Problems which affect how the liver works normally

**Not known** (frequency cannot be estimated from the available data):

- Fainting
- 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
- Blurred vision
- Visual impairment
- 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 level in diabetic patients
  - increase levels of liver enzymes
- Abnormal ECG heart trace
- Metabolic acidosis (excess of acid in your blood)

**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 at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

By reporting side effects, you can help provide more information on the safety of this medicine.

**5. HOW TO STORE INDAPAMIDE TABLETS**

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

Do not store the tablets above 25°C. Store in the original container (in case of Tablet containers) or in the original package (in case of blisters). Keep them in the original pack. Do not use this medicine after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.

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. CONTENTS OF THE PACK AND OTHER INFORMATION****What Indapamide Tablets contains:**

The active substance is Indapamide. The other ingredients are Lactose monohydrate, Maize Starch, Povidone, Magnesium Stearate, Polyvinyl Acetate Phthalate, Stearic acid, Purified Talc, Calcium Carbonate, Acacia, Sucrose, Opaseal, Opaglos 6000 P, Industrial Methylated Spirit, Ethyl Acetate and Titanium Dioxide E171.

**What Indapamide Tablets look like and contents of the pack:**

Indapamide 2.5 mg tablets are white, biconvex, sugar-coated tablet.

**Pack sizes:**

28, 30, 50, 56, 60 and 100 tablets in blisters and 30, 50, 60, 100 and 250 in containers.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder:**

Special Concept Development (UK) Ltd., Unit 1-7 Colonial Way, Watford, Hertfordshire, WD24 4YR. UK.

**Manufacturer:**

Kieva S. A., 189, Parnithos Avenue, 13675 Athens, Greece.

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