

## PACKAGE LEAFLET: INFORMATION FOR THE USER

## INDAPAMIDE 2.5MG TABLETS

## 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 symptoms 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.
- Your doctor may have given you this medicine before from another company. It may have looked slightly different. However, either brand will have the same effect.

**What is in this leaflet:**

1. What indapamide is and what it is used for
2. What you need to know before you take indapamide
3. How to take indapamide
4. Possible side effects
5. How to store indapamide
6. Contents of the pack and other information

**1. WHAT INDAPAMIDE IS AND WHAT IT IS USED FOR**

The name of your medicine is Indapamide 2.5mg Tablets (called indapamide throughout this leaflet). It belongs to a group of medicines called diuretics (water tablets).

**Indapamide can be used for treating:**

- High blood pressure (hypertension). It may be used on its own or in combination with other medicines for high blood pressure.

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. In addition, indapamide widens blood vessels so that blood passes through more easily. This helps lower blood pressure.

**2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE INDAPAMIDE****Do not take indapamide if you:**

- are allergic (hypersensitive) to indapamide, any other sulfonamide or to any of the other ingredients of this medicine (listed in section 6)
- have severe kidney disease
- have severe liver disease or suffer from a condition called hepatic encephalopathy (liver problems which affect your brain and central nervous system)
- have low levels of potassium in your blood (hypokalaemia)

Do not take the medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking indapamide.

**Warnings and precautions**

Talk to your doctor or pharmacist before taking indapamide if you:

- suffer from gout
  - have diabetes
  - have kidney problems
  - have any heart rhythm problems
  - have liver problems
  - experience a decrease in vision or eye pain
- These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to weeks of taking indapamide. This can lead to permanent vision loss, if not treated. If you have had a penicillin or sulfonamide allergy previously, you can be at higher risk of developing this.
- have muscle disorders including muscle pain, tenderness, weakness or cramps
  - 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 medicines, 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**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because indapamide can affect the way some medicines work. Also some medicines can affect the way indapamide works.

You should not take indapamide with lithium (used to treat depression) due to the risk of increased levels of lithium in the blood.

In particular, tell your doctor if you are taking any of the following medicines as special care may be required:

- medicines for heart rhythm problems (quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, ibutilide, dofetilide, digitals or bretylium)
- bepridil (used to treat angina pectoris, a condition causing chest pain)
- stimulant laxatives
- medicines used to treat mental disorders such as depression, anxiety or schizophrenia (for example tricyclic antidepressants, antipsychotic drugs, neuroleptics such as amisulpride, sulpride, sultopride, tiapride, haloperidol, droperidol)
- sparfloxacin, moxifloxacin, erythromycin by injection (antibiotics used to treat bacterial infections)
- vincamine by injection (used to treat symptomatic cognitive disorders in elderly including memory loss)
- pentamidine (used to treat certain types of pneumonia)
- halofantrine (antiparasitic drug used to treat certain types of malaria)
- 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 (aspirin)
- angiotensin converting enzyme (ACE) inhibitors (used to treat high blood pressure and heart failure)
- amphotericin B by injection (anti-fungal medicines)
- oral corticosteroids used to treat various conditions including severe asthma and rheumatoid arthritis
- allopurinol (for the treatment of gout)
- 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)
- cisapride (used to treat reduced movement of the gullet and stomach)
- diphemanil (used to treat gastro-intestinal problems such as ulcers, too much acid, overactive digestive system)
- methadone (used to treat addiction)
- antihistamines used to treat allergic reaction such as hay fever (e.g. mizolastine, astemizole, terfenadine).

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking indapamide.

**Driving and using machines:**

This medicine can cause side effects such as tiredness or dizziness due to lowering of the blood pressure (see section 4). These side effects are more likely to occur after the 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.

**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.

Indapamide 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.

Do not use this medicine if you are breast-feeding or planning to breast-feed. The active ingredient is excreted in milk.

**Important information about the ingredients of indapamide****Indapamide contains lactose and sodium.**

If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicinal product.

Indapamide contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

**3. HOW TO TAKE INDAPAMIDE**

Always take indapamide exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

**Taking this medicine**

- Keep taking this medicine until your doctor tells you to stop. It may take several months before this medicine shows its full effect.
- Treatment for high blood pressure is usually life-long.

- The usual dose is one tablet, once a day, taken in the morning.
- Tablets can be taken with or without food.
- Swallow the tablets whole with a drink of water.

#### **If you take more indapamide than you should**

If you take more tablets than you should, tell your doctor or go to your nearest hospital casualty department immediately.

Take the carton and any indapamide tablets left with you so that the doctors know what you have taken.

Taking too much indapamide may make you feel or be sick (nausea or vomiting), cause low blood pressure, cramps, dizziness, drowsiness, confusion and changes in the amount of urine produced by the kidneys due to severe dehydration.

#### **If you forget to take indapamide**

Do not take a double dose to make up for a forgotten tablet. Miss it out and take the next dose at the usual time.

#### **If you stop taking indapamide**

Keep taking indapamide until your doctor tells you to stop taking it. Treatment for high blood pressure is usually life-long.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## **4. POSSIBLE SIDE EFFECTS**

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

### **Stop taking indapamide and see your doctor immediately or go to a hospital straight away if you experience any of the following side effects that can be serious:**

- Angioedema and/or urticaria. Angioedema is characterised by swelling of the skin of extremities or face, swelling of the lips or tongue, 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 (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 (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);
- Disease of the brain caused by liver illness (Hepatic encephalopathy) (Not known);
- Inflammation of the liver (Hepatitis) (Not known);
- Muscle weakness, cramps, tenderness or pain and particularly, if at the same time, you feel unwell or have a high temperature as it may be caused by an abnormal muscle breakdown (Not known).

In decreasing order of frequency, other side effects can include:

#### **Common (may affect up to 1 in 10 people):**

- Red raised skin rash;
- Allergic reactions, mainly dermatological, such as skin rashes in patients with a predisposition to allergic and asthmatic reactions;
- Low potassium in the blood.

#### **Uncommon (may affect less than 1 in 100 people):**

- Being sick (vomiting);
- Red pinpoint on skin (purpura);
- Low sodium in the blood that may lead to dehydration and low blood pressure;
- Impotence (inability to obtain or maintain an erection).

#### **Rare (may affect less than 1 in 1,000 people):**

- Feeling of tiredness, headache, pins and needles (paresthesia), vertigo;
- Gastro-intestinal disorders such as nausea (feeling sick) constipation, dry mouth;
- Low chloride in the blood;
- Low magnesium in the blood.

#### **Very rare (may affect less than 1 in 10,000 people):**

- 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);
- High level of calcium in the blood;
- 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);
- Abnormal hepatic function.

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

- 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 also been reported;
- Short sightedness (myopia);
- Blurred vision;
- Visual impairment;
- Decrease in vision or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute angle-glaucoma);
- 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 joints especially in the feet),
  - increase in blood glucose levels in diabetic patients,
  - increased levels of liver enzymes,
- Abnormal ECG heart trace.

#### **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) or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

## **5. HOW TO STORE INDAPAMIDE**

- Keep this medicine out of the sight and reach of children.
- Do not use indapamide after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
- Do not use indapamide if you notice that the tablets are crumbling, broken or discoloured.
- Indapamide tablets do not need any special storage conditions.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What Indapamide 2.5mg Tablets contain**

- Each tablet contains 2.5mg of the active substance, Indapamide hemihydrate.
- The other ingredients are microcrystalline cellulose, magnesium stearate, lactose, croscarmellose sodium, hypromellose, macrogol 400 and titanium dioxide.

### **What Indapamide 2.5mg Tablets look like and contents of the pack**

The tablets are white, round film coated, 6 mm diameter, normal biconvex tablets, embossed with “S6” one side and blank on the reverse.

Pack sizes: 28, 30, 56, 60.

Not all pack sizes are marketed.

#### **Marketing Authorisation Holder**

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#### **Manufacturer**

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