

Indapamide Tablets USP 1.5mg/1.25mg/2.5mg

(Indapamide)

PATIENT INFORMATION LEAFLET

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 medicine 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:

- if you are allergic (hypersensitive) to indapamide, any other sulfonamide or to 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 your brain and central nervous system)
- if you 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 or have diabetes
- if you have kidney problems
- if you have an overactive thyroid gland (hyperparathyroidism)
- if you have heart rhythm problems
- if you have liver problems

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.

Athletes should be aware that this medicine contains an active ingredient, which may give a positive reaction in doping tests.

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.

Other medicines and indapamide

Please 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.

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

- lithium (used to treat depression). You should not take indapamide with lithium due to the risk of increased levels of lithium in the blood
- medicines for heart rhythm problems such as quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, ibutilide, dofetilide or digitalis
- 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)
- sparfloxacin, moxifloxacin, erythromycin by injection (antibiotics used to treat 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)

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.

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

Pregnancy and breast-feeding

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.

- Talk to your doctor before taking this medicine if you are pregnant, might become pregnant, think you may be 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.

Indapamide contains lactose.

If you have been told by your doctor that you cannot digest or tolerate some sugars, talk to your doctor before taking this medicine.

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.
- Tablets can be taken with or without food
- Swallow the tablets whole with a drink of water

Adults and Elderly

The usual dose is one tablet, once a day, taken in the morning

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:

- Angioedema and/or urticaria. Angioedema is characterised by swelling of the skin around the eyes, lips, tongue, 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;
- 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), flu-like symptoms and fever or other allergic reactions;
- You get an irregular heartbeat (Torsade de pointes), which could be life-threatening;

- Severe stomach pain which may reach through to your back. This could be a sign of pancreatitis;
- 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).

Tell your doctor as soon as possible if you have any of the following side-effects:

- You feel tired, weak, confused and have muscles that ache, are stiff or do not work well. This may be due to low sodium levels in your blood (hyponatraemia)
- You feel irritable and your muscles twitch. This may be due to an imbalance in your blood called metabolic alkalosis
- Itchy, lumpy rash. You may also have a high temperature, sore throat, headache or diarrhoea
- You get more infections than usual or bruise more easily. This could be caused by problems with your blood.
- You get increased thirst, hunger and weight loss. These could be signs of diabetes

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days. Also tell them if you notice any side effects not listed in this leaflet.

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.

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

- Being sick (vomiting);

- Red pinpoints on skin (purpura).

Rare (may affect less than 1 in 1000 people):

- Feeling of tiredness, headache, pins and needles (paresthesia), vertigo;
- Gastro-intestinal disorders such as nausea (feeling sick) or constipation, dry mouth;

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

- 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);
- 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.
- Abnormal hepatic function.

Not known:

- Fainting;
- Visual impairment such as short sightedness (myopia) and blurred vision;
- Dizziness, lightheadedness, fainting when you stand or sit up quickly (due to low blood pressure) loss of appetite (anorexia), indigestion;
- Abnormal ECG heart trace;
- Hepatitis;
- Low potassium in the blood, which may cause muscle weakness;
- The following changes in your blood test results may occur:
 - increase in uric acid, a substance which may cause or worsen gout (painful joints especially in the feet)

- increased levels of liver enzymes

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.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

5. How to store indapamide

Keep out of the reach and sight 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.

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. Contents of the pack and other information

What Indapamide Tablets contain

a) Each tablet contains:	
Indapamide USP	1.5mg
Excipients	q.s.
b) Each tablet contains:	
Indapamide USP	1.25mg
Excipients	q.s.
c) Each tablet contains:	
Indapamide USP	2.5mg
Excipients	q.s.

The other ingredients are microcrystalline cellulose, magnesium stearate, lactose, croscarmellose sodium, hypromellose, macrogol and titanium dioxide.

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

Round, white, film-coated tablet.

White, opaque PVC/aluminium foil blister packs.

Pack sizes: 7, 14, 28, 30, 50, 90, 100 and 500 tablets.

Not All Packs May be Marketed.

7. Manufactured In India By:

TAJ PHARMACEUTICALS LTD.

Mumbai, India

Unit No. 214.Old Bake House,
Maharashtra chambers of Commerce Lane,
Fort, Mumbai - 400001
at:Gujarat, INDIA.

Customer Service and Product Inquiries:

1-800-TRY-FIRST (1-800-222-434 & 1-800-222-825)

Monday through Saturday 9:00 a.m. to 7:00 p.m.
EST

E-mail: tajgroup@tajpharma.com