



PACKAGE LEAFLET: INFORMATION FOR THE USER

INDAPAMIDE TABLETS 2.5 mg

[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

Indapamide Tablets contain the active substance indapamide. Indapamide is a diuretic and is intended to reduce high blood pressure (hypertension) in adults. 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 to lower blood pressure.

2. What you need to know before you take Indapamide Tablets

Do not take Indapamide Tablets:

- If you are allergic to indapamide or 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 the brain and central nervous system)
 - If you have low potassium levels in your blood (hypokalaemia)
 - If you have high calcium levels in your blood (hypercalcaemia)
 - If you have low sodium levels in your blood (hyponatraemia)
 - If you have a rare inherited blood disease called porphyria
 - If you have an illness called Addison's disease.
- 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.

Warnings and precautions

Talk to your doctor, pharmacist, or nurse before taking Indapamide Tablets:

- If you have liver or kidney problems
- If you have diabetes
- If you suffer from gout
- If you have any heart rhythm problems
- If you need to have a test to check how well your parathyroid gland is working
- If you are taking thiazides or thiazide related diuretics as photosensitivity may occur.
- If you 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 a week of taking Indapamide Tablets. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulfonamide allergy, you can be at higher risk of developing this.

Keep out of direct sunlight while taking this medicine and for a few months after you have finished taking it. This is because your skin will become much more sensitive to the sun and may burn, tingle or severely blister if you do not take the following precautions:

- Make sure you use high factor sun cream
- Always wear a hat and clothes which cover your arms and legs.

Indapamide may lower potassium levels and your doctor may monitor this by means of blood tests. This may happen in patients receiving multiple treatments or in the elderly, or in those suffering from cirrhosis of the liver, with fluid retention, or from prolonged or severe diarrhoea, or hyperaldosteronism

(over production of a hormone that controls sodium and potassium levels in the blood).

Blood calcium levels may need to be monitored in those patients suffering from overactivity of the parathyroid gland. Please inform your doctor or pharmacist if you suffer from gout. Indapamide may cause the blood uric acid levels to increase when treatment is commenced.

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

Children and adolescents

Indapamide Tablets are not recommended for use in children and adolescents.

Other medicines and Indapamide Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, in particular any of the following:

- Medicines used for heart rhythm problems (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, ibutilide, dofetilide, bretylium, digitalis), methadone, astemizole, terfenadine. Increased risk of ventricular arrhythmias, particularly torsades de pointes (hypokalaemia is a risk factor).
- Medicines used to treat mental disorders such as depression, anxiety, schizophrenia (e.g. tricyclic antidepressants, antipsychotic drugs such as lithium, neuroleptics)
- Bepridil (used to treat angina pectoris, a condition causing chest pain)
- 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)
- Sparfloxacin, moxifloxacin, erythromycin by injection (antibiotics used to treat infections)
- Vincamine by injection (used to treat symptomatic cognitive disorders in the elderly, including memory loss)
- Halofantrine (antiparasitic drug used to treat certain types of malaria)
- Pentamidine (used to treat certain types of pneumonia)
- 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
- 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
- Amphotericin B by injection (anti-fungal medicines)
- Stimulant laxatives
- Baclofen (to treat muscle stiffness occurring in diseases such as multiple sclerosis)
- Allopurinol (for the treatment of gout)
- 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).

Indapamide Tablets with food and drink

Indapamide Tablets should be swallowed with a glass of water. It is advised that the tablet be taken in the morning before breakfast.

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 in small amounts.

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

No effects on human fertility are anticipated.

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

150 x 310 mm

FRONT SIDE PRINTING

ARTWORK DETAIL LABEL

Product	INDAPAMIDE TABLETS 2.5 mg				
Buyer/Country	Strides Pharma UK Ltd.	Component	Pack Insert		
Dimension	150 x 310 mm		Pack	--	
New Item Code	1046552	Old Item Code	1046119		
Colour Shades	■ BLACK		No. of Colours	1	
Change Control No.	PC-TSG/2021/451 - Record Number: 323561			Artwork Version	11.0
Design/Style	Front & Back Printing. To be supplied in the unfolded size.				
Substrate	60 GSM Paper.				
Special Instructions	Printing clarity to be clear & sharp.				
Autocartonator Requirements	Pack insert supply should be as per auto-cartonator. Refer auto-cartonator drawing for instructions.				

Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. **DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.**

refrain from driving and other activities requiring alertness. However, under good control, these side effects are unlikely to occur.

Indapamide Tablets contain 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 medicine.

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 recommended dose is one tablet each day which should be swallowed with a glass of water. It is advised that the tablet be taken in the morning before breakfast. Treatment for high blood pressure is usually life-long.

Use in children and adolescents

Indapamide Tablets are not recommended for use in children and adolescents.

Use in the elderly

Only treat elderly patients who have normal kidney function or slightly impaired function.

If you take more Indapamide Tablets than you should

If you have taken too many tablets, contact your doctor or nearest hospital casualty department immediately.

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 one or more doses, take another as soon as you remember and then go on as prescribed.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Indapamide Tablets

As the treatment for high blood pressure is usually life-long, you should discuss with your doctor before stopping this medicine.

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.

If you experience any of the following then STOP taking the medicine and contact a doctor immediately:

- 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.
 - 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.
 - Life-threatening irregular heart beat
 - Inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell
 - Disease of the brain caused by liver illness (hepatic encephalopathy)
 - Inflammation of the liver (hepatitis).
- 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 subjects with a predisposition to allergic and asthmatic reactions.
- Low potassium in the blood

Uncommon (may affect up to 1 in 100 people)

- Vomiting
- Red pinpoints 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 up to 1 in 1,000 people)

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

Very rare (may affect up to 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 in 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 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)
- 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-closure glaucoma)
- 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:
 - 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
- Abnormal ECG heart tracing
- Muscle cramps, Muscle spasms, Muscular weakness, Myalgia, Rhabdomyolysis.
- Weakness (asthenia)
- Impotence
- Weight loss.

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 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 Tablets

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

Do not store above 25°C. Store in the original package.

If your doctor decides to stop the treatment, return any tablets left over to the pharmacist. Only keep them if your doctor tells you to.

Do not use this medicine after the expiry date which is stated on the label. 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 contain

The active substance is indapamide. Each tablet contains 2.5mg indapamide. The other ingredients are: lactose (see section 2), maize starch, polyvidone, magnesium stearate, Opaseal (containing polyvinylacetate phthalate, ethyl acetate and stearic acid), purified talc, calcium carbonate, acacia, titanium dioxide (E171), sucrose (see section 2), Opaglos 6000P (containing shellac, carnauba wax yellow and beeswax white).

What Indapamide Tablets look like and contents of the pack

Description: White, biconvex, sugar coated tablet.

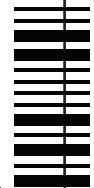
Contents of pack: Indapamide Tablets are supplied in pack sizes of 28, 30, 50, 56, 60, 100 and 120 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

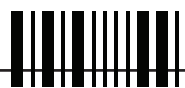
Strides Pharma UK Ltd.
Unit 4, Metro Centre, Tolpits Lane,
Watford, Herts. UK, WD18 9SS
Tel: 01923 255580
Fax: 01923 255581

This leaflet was last revised in December 2021.



9748

1046552



876

150 x 310 mm

BACK SIDE PRINTING

ARTWORK DETAIL LABEL

Product	INDAPAMIDE TABLETS 2.5 mg			
Buyer/Country	Strides Pharma UK Ltd.	Component	Pack Insert	
Dimension	150 x 310 mm		Pack	--
New Item Code	1046552	Old Item Code	1046119	
Colour Shades	■ BLACK		No. of Colours	1
Change Control No.	PC-TSG/2021/451 - Record Number: 323561		Artwork Version	11.0
Design/Style	Front & Back Printing. To be supplied in the unfolded size.			
Substrate	60 GSM Paper.			
Special Instructions	Printing clarity to be clear & sharp.			
Autocartonator Requirements	Pack insert supply should be as per auto-cartonator. Refer auto-cartonator drawing for instructions.			

Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. **DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.**