

INDAPAMIDE SR TABLET

Indapamide 1.5mg

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What Indapamide SR is used for

Indapamide is indicated for the treatment of high blood pressure (Essential Hypertension).

How Indapamide SR works

Indapamide is an oral antihypertensive agent. It removes excess water from the body by increasing how often you urinate (pass water). Indapamide SR is a modified release preparation available as tablet, which means Indapamide SR is released slowly over the day to give an even effect. Removing water from the blood decreases the volume of fluid circulating through the blood vessels. The drop in fluid volume results in a drop in the pressure of the fluid within the blood vessels, which helps to lower high blood pressure. It also decreases the effort required by the heart to pump blood around the body.

Before you use Indapamide SR

- When you must not use it
- If you have severe renal failure

- If you are having low concentration of potassium (K⁺) in the blood (Hypokalaemia) or severe impairment of liver function.
- Known hypersensitivity to indapamide or to other sulphonamide derivatives

Pregnancy and lactation

Do not take Indapamide SR if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Indapamide SR if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Take special care if you have:

- Low concentration of sodium (hyponatraemia)
- Irregular heartbeat (arrhythmias)
- High levels of calcium in the blood (hypercalcaemia)
- High level of uric acid
- Decreased kidney function
- Elderly people
- Over activity of the parathyroid glands (hyperparathyroidism)

If you are athletes then the active ingredient of this drug may give a positive reaction in doping test.

This medication is not indicated for children. Please consult doctor before use it.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Combinations that are not recommended

Lithium: Increased plasma lithium with signs of overdose, as with a salt-free diet (decreased urinary lithium excretion).

Combinations requiring precautions for use

Torsades de pointes-inducing drugs:

- Class Ia antiarrhythmics (quinidine, hydroquinidine, disopyramide),
- Class III antiarrhythmics (amiodarone, sotalol, dofetilide, ibutilide),
- Some antipsychotics: phenothiazines (chlorpromazine, cyamemazine, levomepromazine, thioridazine, trifluoperazine), Benzamides (amisulpride, sulpiride, sultopride, tiapride), Butyrophenones (droperidol, haloperidol);
- Others: bepridil, cisapride, diphemanil, erythromycin IV, halofantrine, mizolastine, pentamidine, sparfloxacin, moxifloxacin, vincamine IV.

N.S.A.I.Ds. (systemic route)

including COX-2 selective inhibitors, high dose salicylic acid (≥ 3 g/day):

Possible reduction in the antihypertensive effect of indapamide (example of NSAIDs are aspirin, ibuprofen, and naproxen). Risk of acute renal failure in dehydrated patients.

Angiotensin converting enzyme (A.C.E.) inhibitors:

Risk of sudden hypotension and/or acute renal failure when treatment with an A.C.E. inhibitor is initiated in the presence of preexisting sodium

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depletion (Example of ACE inhibitors are perindopril, captopril, enalapril, lisinopril, and ramipril).

Other compounds:

Medicines that may increase risk of hypokalaemia when used with indapamide:

- Amphotericin B (IV)
- Gluco-and mineralo-corticoids (systemic route),
- tetracosactide,
- stimulant laxatives

Medicines that may increase risk of hypokalaemia or hyperkalaemia when used with indapamide:

- Potassium-sparing diuretics (Like amiloride, spironolactone, triamterene)

Medicine that may lead to lactic acidosis:

- Metformin

Others

- Imipramine-like antidepressants,
- neuroleptics;
- Cyclosporine, tacrolimus;
- Corticosteroids, tetracosactide

How to use Indapamide SR

- How much to use

One tablet per 24 hours. At higher dose the antihypertensive action of indapamide is not enhanced but the saluretic effect (A drug that promotes excretion of salt in the urine) is increased.

- When to use it

Preferably in the morning, to be swallowed whole swallowed with water and not chewed.

- How long to use it

Continue taking Indapamide SR for as long as your doctor recommends.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Taking too many tablets may cause nausea, vomiting, hypotension, cramps, vertigo, drowsiness, confusion, excessive or abnormally large production of urine

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Indapamide SR.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Indapamide SR to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or fatigue, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

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

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

The following are some of the side effects that are known to be associated with this medicine.

- Decrease of platelets in blood (Thrombocytopenia), decrease in the number of white blood cells (leucopenia), lowered white blood cell count (agranulocytosis), deficiency of all three blood cell types red blood cells, white blood cells and platelets [aplastic anaemia]
- Vertigo, fatigue, headache, paresthesia
- Arrhythmia, hypotension
- Nausea, constipation, pancreatitis
- Abnormal liver function
- Hypersensitivity reactions, maculopapular rashes, purpura
- Hypercalcaemia

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- Potassium depletion with Low concentration of potassium in blood (hypokalaemia)
- Metabolic alkalosis (Increase in pH of tissues from normal range).
- Increase in plasma uric acid and blood glucose.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and disposal of Indapamide SR

- Storage
Store in dry place. Store below 25°C.
- Disposal
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

Product description

- What it looks like
White to off-white, round shaped, biconvex film-coated tablet.
- Ingredients
 - Active ingredient(s)
Indapamide
 - Inactive ingredients
Lactose Monohydrate
Pre gelatinized Starch
Hypromellose
Colloidal Silicon Dioxide
Magnesium Stearate
Macrogol
Titanium Dioxide

- MAL number(s):
MAL07061382A

Manufacturer

TORRENT
PHARMACEUTICALS LTD.
Indrad 382 721, District:
Mehsana, INDIA.

Product Registration Holder

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10/07/2014