APPROVED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

INDAPAMIDE 1.5 mg SR PD sustained release tablets

Indapamide

INDAPAMIDE 1.5 mg SR PD contains sugar (lactose monohydrate 91,125 mg per tablet).

Read all of this leaflet carefully before you start taking INDAPAMIDE 1.5 mg SR PD

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other healthcare provider.
- INDAPAMIDE 1.5 mg SR PD has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What INDAPAMIDE 1.5 mg SR PD is and what it is used for

INDAPAMIDE 1.5 mg SR PD contains indapamide, one of a group of medicines called vasodilators.

INDAPAMIDE 1.5 mg SR PD is prescribed by doctors to treat high blood pressure.

2. What you need to know before you take INDAPAMIDE 1.5 mg SR PD

Do not take INDAPAMIDE 1.5 mg SR PD:

- if you are hypersensitive (allergic) to indapamide, other sulphonamide type medications (also called sulfa medications and used for the treatment of different infections), or any of the other ingredients of INDAPAMIDE 1.5 mg SR PD (see section 6)

  Please inform your doctor if you are allergic to sulphonamide type medicines (sulfa medications), especially if you have had incidents of allergic reactions after receiving such medicines

- if you have severe liver disease or suffer from a condition called hepatic encephalopathy (degenerative disease of the brain)
- if you have severe kidney failure
- if you have low potassium levels in your blood.

Warnings and precautions

Special care should be taken with INDAPAMIDE 1.5 mg SR PD:

- if you are elderly, as you may be more sensitive to the electrolyte and blood pressure lowering effect of INDAPAMIDE 1.5 mg SR PD
- if you have kidney damage or are unable to urinate
- if you have diabetes, monitoring of blood glucose (blood sugar) is important in the presence of hypokalaemia
- if you suffer from gout, which may worsen due to increased levels of uric acid in the blood
- if you have any damage to your liver resulting in loss of liver function
- if you had a sympathectomy (operation to block a nerve in the middle of your body to treat conditions such as excessive sweating or severe facial flushing/blushing)
- if you have electrolyte imbalance due to dehydration. Your doctor may check for low sodium, magnesium or potassium levels or high calcium levels
- if you have an irregular heart rhythm condition

- if you are taking other diuretics while taking INDAPAMIDE 1.5 mg SR PD it may cause hypokalaemia, and is not recommended (see INTERACTIONS section 4.5)
- if your liver does not function properly, INDAPAMIDE 1.5 mg SR PD should not be taken
- if you have a photosensitivity reaction while taking INDAPAMIDE 1.5 mg SR PD. If you have to continue taking the medication, it is recommended to protect exposed areas to the sun or to artificial UVA
- if you have rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption, you should not take this medicine
- if you are an athlete, you must be aware of the fact that this medicinal product contains an ingredient which may give a positive reaction in doping tests
- 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 weeks of taking INDAPAMIDE 1.5 mg SR PD.

Children and adolescents

Children: Safety and efficacy have not been established and INDAPAMIDE 1.5 mg SR PD is not recommended for use in children.

Other medicines and INDAPAMIDE 1.5 mg SR PD

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

- lithium (used to treat depression), due to increased levels of lithium in the blood
- the following medicines, if used with INDAPAMIDE 1.5 mg SR PD, can cause serious abnormal heart rhythm:
    - medications used for heart rhythm problems (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, ibutilide, dofetilide)
    - medications used to treat mental disorders such as depression, anxiety, schizophrenia, some antipsychotics: phenothiazines (chlorpromazine, cyamemazine, levomepromazine, thioridazine, trifluoperazine), benzamides (amisulpride, sulpiride, sultopride, tiapride) butyrophenones (droperidol, haloperidol)
    - other medicines - bepridil (to treat angina), cisapride (to treat gastric reflux), diphemanil (treat excessive sweating), antibiotics -erythromycin IV, sparfloxacin and moxifloxacin, halofantrine (to treat malaria), mizolastine (anti-allergy medicine), pentamidine (to treat pneumonia), vincamine IV (to treat high blood pressure)
- Non-Steroidal Anti-inflammatory Drugs for pain relief (e.g. ibuprofen) or high doses of aspirin may decrease effect of INDAPAMIDE 1.5 mg SR PD

- Angiotensin Converting Enzyme (ACE) inhibitors, e.g. enalapril, ramipril (used to treat high blood pressure and heart failure) may increase effect of INDAPAMIDE 1.5 mg SR PD
- stimulant laxatives, such as senna and bisacodyl (used to encourage bowel movements)
- baclofen (to treat muscle stiffness occurring in diseases such as multiple sclerosis) may increase the effect of INDAPAMIDE 1.5 mg SR PD
- allopurinol (for the treatment of gout), as hypersensitivity/allergic reactions may be increased
- digoxin (to treat angina) – toxic effects may be increased
- potassium-sparing diuretics – water tablets (amiloride, spironolactone, triamterene)
- metformin (used in the treatment of diabetes) results in an increased risk of lactic acidosis (too much lactic acid in the body) with symptoms such as stomach discomfort, muscle pain, muscle cramping, unusual tiredness or weakness
- iodinated contrast media (used for tests involving X-rays) increase the risk of kidney disease
- imipramine (to treat depression) may increase risk of low blood pressure when getting up from a lying or sitting position
- calcium tablets or other calcium supplements may increase calcium levels in the blood

- ciclosporin, tacrolimus or other medicines to depress the immune system after organ transplantation, to treat autoimmune diseases, or severe rheumatic or dermatological diseases
- corticosteroids, tetracosactide (to treat Crohn's disease), decreases the effect of INDAPAMIDE 1.5 mg SR PD.

INDAPAMIDE 1.5 mg SR PD with food and drink and alcohol

INDAPAMIDE 1.5 mg SR PD can be taken with or without food.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before INDAPAMIDE 1.5 mg SR PDtaking this medicine.

DO NOT take INDAPAMIDE 1.5 mg SR PD if you are pregnant or suspect that you are pregnant.

Contact your doctor immediately.

DO NOT take INDAPAMIDE 1.5 mg SR PD if you are breastfeeding.

Driving and using machines

INDAPAMIDE 1.5 mg SR PD can cause side effects due to lowering of the blood pressure such as dizziness or tiredness (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 refrain from driving and other

activities requiring alertness. However, under good control, these side effects are unlikely to occur.

It is not always possible to predict to what extent INDAPAMIDE 1.5 mg SR PD may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which INDAPAMIDE 1.5 mg SR PD affects them.

INDAPAMIDE 1.5 mg SR PD contains lactose monohydrate

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 1.5 mg SR PD

Do not share medicines prescribed for you with any other person.

Always take INDAPAMIDE 1.5 mg SR PD exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults:

The usual dose is one INDAPAMIDE 1.5 mg SR PD tablet every day, preferably taken on arising in the morning.

The tablet should be swallowed whole with water and not chewed, preferably taken when waking in the morning.

Your doctor will tell you how long your treatment with INDAPAMIDE 1.5 mg SR PD will last. If you have the impression that the effect of INDAPAMIDE 1.5 mg SR PD is too strong or too weak, tell your doctor or pharmacist.

If you take more INDAPAMIDE 1.5 mg SR PD than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Symptoms of overdose may include:

- water/electrolyte disturbances, nausea, vomiting, low blood pressure, cramps, vertigo, drowsiness, confusion, increased urination, decreased urination polyuria or oliguria possibly to the point of anuria (when the kidneys aren't producing urine)

If you forget to take INDAPAMIDE 1.5 mg SR PD

If you forget to take INDAPAMIDE 1.5 mg SR PD, take a dose as soon as you remember, then continue to take INDAPAMIDE 1.5 mg SR PD at the usual times. Do not take a double dose to make up for forgotten individual doses.

If you stop taking INDAPAMIDE 1.5 mg SR PD

The treatment for high blood pressure is usually life-long and you should discuss with your doctor before stopping this medicinal product.

4. Possible side effects

INDAPAMIDE 1.5 mg SR PD can have side effects.
Not all side effects reported for INDAPAMIDE 1.5 mg SR PD are included in this leaflet.
Should your general health worsen, or if you experience any untoward effects while using INDAPAMIDE 1.5 mg SR PD, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using INDAPAMIDE 1.5 mg SR PD and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching

- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to INDAPAMIDE 1.5 mg SR PD. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- difficulty breathing, shortness of breath, tight chest
- abnormal heart rhythm which can lead to sudden cardiac death
- reduced liver function with symptoms such as abdominal pain or swelling, jaundice, nausea and vomiting, diagnosed with hepatitis (viral infection of the liver) (viral infection of the liver, cholestatic jaundice (symptoms include yellow skin or eyes)
- toxic epidermic necrolysis and Stevens-Johnson syndrome (fever and flu-like symptoms a flat red rash followed by skin blisters and peeling, and blisters and sores on the mucous membranes)
- kidney failure, symptoms include loss of appetite and fatigue
- pancreatitis (inflammation of the pancreas with symptoms that include severe abdominal and back pain accompanied with feeling very unwell)
- disease of the brain caused by liver illness (Hepatic encephalopathy) with symptoms that may include confusion, fatigue, flapping hand tremor, sleepiness, bad breath from liver disease, irritability, memory loss, or slurred speech

- 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)
- rhabdomyolysis (a serious medical condition that can be fatal or result in permanent disability, symptoms include muscle cramps, aches, or pains that are more severe than expected, dark urine (tea- or cola-coloured), feeling weak or tired, unable to complete job tasks or finish a workout routine).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- both flat and raised ‘bumps’ on the skin.

Less frequent side effects:

- abnormal blood counts, anaemia, tendency to bleed easily, 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)
- headaches, dizziness especially when standing up from lying or sitting position), tiredness, ‘pins and needles’ feeling on the skin
- low blood pressure

- anorexia (eating disorder characterized by low body weight), stomach pain, gas and bloatedness, nausea, vomiting, constipation, diarrhoea, dry mouth
- discolouration of the skin produced by small bleeding vessels, urticaria or hives (a kind of skin rash with red, raised, itchy bumps)
- erectile dysfunction.

The following side effects have been reported but the frequency for them to occur is not known:

- electrolyte imbalance – sodium, potassium (symptoms such as tiredness and leg cramps), calcium
- short sightedness, blurred vision, vision loss
- possible worsening of pre-existing acute disseminated lupus erythematosus (collection of autoimmune diseases in which the immune system attacks healthy tissues), photosensitivity reactions (an extreme sensitivity to ultraviolet (UV) rays from the sun and other sources of light)
- abnormal electrocardiogram (showing the heartbeat pattern), blood tests showing increased glucose/sugar levels, uric acid and liver enzyme levels
- muscle weakness, spasms or pain.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of INDAPAMIDE 1.5 mg SR PD. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store INDAPAMIDE 1.5 mg SR PD

Store all medicines out of reach of children.

Store at or below 30 °C in original container.

Do not remove the blisters from the outer carton until required for use.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What INDAPAMIDE 1.5 mg SR PD contains

The active substance is Indapamide.

Each tablet contains 1.5 mg Indapamide.

The other ingredients are

Cellactose (a combination of alpha-lactose monohydrate and cellulose powder), hypromellose, magnesium stearate, opadry Y-1-7000 (a combination of hypromellose, macrogol 400 and titanium dioxide), silica (colloidal anhydrous).

What INDAPAMIDE 1.5 mg SR PD looks like and contents of the pack

INDAPAMIDE 1.5 mg SR PD film coated tablets are white, round, slightly biconvex film tablets. It is packed in aluminium foil and transparent, hard PVC/PVDC foil blister strips of 3 x 10 tablets inside an outer carton box.

Holder of Certificate of Registration

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For access to the Professional Information, please visit

www.pharmadynamics.co.za