INDAPAMIDE 1,5 mg SR PD

SCHEDULING STATUS S3

1. NAME OF THE MEDICINE
INDAPAMIDE 1,5 mg SR PD sustained release tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each sustained release tablet contains 1,5 mg indapamide.
INDAPAMIDE 1,5 mg SR PD contains sugar (lactose monohydrate 97,58 mg per tablet).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Sustained release tablets.
INDAPAMIDE 1,5 mg SR PD appears as white, round, slightly biconvex film coated tablets.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
INDAPAMIDE 1,5 mg SR PD is indicated in the management of mild to moderate hypertension.

4.2 Posology and method of administration
Posology
Adults: One tablet daily, to be swallowed whole with water and not chewed, preferably taken on arising in the morning.
INDAPAMIDE 1,5 mg SR PD (1,5 mg indapamide) can be combined with other categories of antihypertensive agents, in more severe cases.
The antihypertensive action of indapamide is not enhanced at higher doses, but the saluretic effect is increased.

Special populations
Renal impairment
In severe renal failure (creatinine clearance below 30 mL/min), treatment is contraindicated (see section 4.3).
Thiazide and related diuretics are fully effective only when renal function is normal or only minimally impaired (see section 4.4).

Hepatic impairment
In severe hepatic impairment, treatment is contraindicated (see sections 4.3 and 4.4).

Elderly
In the elderly, the plasma creatinine must be adjusted in relation to age, weight and gender. Elderly patients can be treated with INDAPAMIDE 1,5 mg SR PD when renal function is normal or only minimally impaired (see section 4.4).

Paediatric population
Safety and efficacy have not been established and INDAPAMIDE 1,5 mg SR PD is not recommended for use in children and adolescents under the age of 18 years as no data are available.

Method of administration
Oral use.

4.3 Contraindications
- hypersensitivity to indapamide, other sulphonamide type medications, or to any of the ingredients of INDAPAMIDE 1,5 mg SR PD
- hepatic encephalopathy or severe hepatic impairment
- in patients with severe renal failure
- in patients with hypokalaemia.

4.4 Special warnings and precautions for use
The elderly patient population may be more sensitive to the electrolyte and hypotensive effects of INDAPAMIDE 1,5 mg SR PD. In addition, elderly patients are more likely to have renal function impairment, which may require caution. The following medical conditions should be considered for risk-benefit when present in patients: severe renal impairment or anuria, history of gout, diabetes mellitus, hyperuricaemia, hepatic impairment and sympathectomy.
Hypersensitivity to other sulphonamide-type medicines may lead to allergic reaction when taking INDAPAMIDE 1,5 mg SR PD.
Laboratory test values that may be altered while taking INDAPAMIDE 1,5 mg SR PD include the following: calcium and protein-bound iodine (decreased); plasma renin activity (increased); potassium and sodium (decreased, but within normal limits); uric acid (increased, but within normal limits).

Special warnings
When liver function is impaired, thiazide-related diuretics may cause hepatic encephalopathy, particularly in case of electrolyte imbalance. Administration of the diuretic must be stopped immediately if this occurs.

Photosensitivity
Cases of photosensitivity reactions have been reported with thiazides and thiazide-related diuretics (see section 4.8). If photosensitivity reaction occurs during treatment, it is recommended to stop the treatment. If a re-administration of the diuretic is deemed necessary, it is recommended to protect exposed areas to the sun or to artificial UVA.

Special precautions for use
Water and electrolyte balance
Plasma sodium:
This must be measured before starting treatment, then at regular intervals subsequently. The fall in plasma sodium may be asymptomatic initially and regular monitoring is therefore essential. Monitoring should be even more frequent in the elderly and cirrhotic patients (see sections 4.8 and 4.9). Any diuretic treatment may cause hyponatraemia, sometimes with very serious consequences.
Hyponatraemia with hypovolaemia may be responsible for dehydration and orthostatic hypotension.
Concomitant loss of chloride ions may lead to secondary compensatory metabolic alkalosis: the incidence and degree of this effect are slight.

Plasma potassium:
Potassium depletion with hypokalaemia is the major risk of thiazide and related diuretics. The risk of onset of hypokalaemia (< 3,4 mmol/L) must be prevented in certain high-risk populations, i.e. the elderly, malnourished and/or polymedicated, cirrhotic patients with oedema and ascites, coronary artery disease and cardiac failure patients. In this situation, hypokalaemia increases the cardiac toxicity of digitalis preparations and the risks of arrhythmias. Individuals with a long QT interval are also at risk, whether the origin is congenital or iatrogenic.
Hypokalaemia, as well as bradycardia, is then a predisposing factor to the onset of severe arrhythmias, in particular, potentially fatal *torsade de pointes*. More frequent monitoring of plasma potassium is required in all the situations indicated above. The first measurement of plasma potassium should be obtained during the first week following the start of treatment.
Detection of hypokalaemia requires its correction.
In patients at risk of developing hypokalaemia, serum potassium should be monitored, and they may require potassium supplements or potassium-sparing diuretics.
Co-administration of INDAPAMIDE 1,5 mg SR PD with other diuretics, which may cause hypokalaemia, is not recommended (see section 4.5).
Hypokalaemia found in association with low serum magnesium concentration can be refractory to treatment unless serum magnesium is corrected.

Plasma magnesium:
Thiazides and related diuretics including indapamide have been shown to increase the urinary excretion of magnesium, which may result in hypomagnesaemia.

Plasma calcium:
Thiazide and related diuretics may decrease urinary calcium excretion and cause a slight and transitory rise in plasma calcium. Frankly, hypercalcaemia may be due to previously unrecognized hyperparathyroidism.
Treatment should be withdrawn before the investigation of parathyroid function.

Uric acid:
Concentrations of serum uric acid should be monitored particularly in patients with a history of gout, who should continue with appropriate treatment.

Mild to moderately impaired renal function:
INDAPAMIDE 1,5 mg SR PD can be administered to hypertensive patients with mild to moderately impaired renal function. If azotaemia or oliguria occurs, the treatment should be discontinued.

Blood glucose:
Monitoring of blood glucose is important in diabetic patients, in particular in the presence of hypokalaemia.

Renal function and diuretics:
Thiazide and related diuretics are fully effective only when renal function is normal or only minimally impaired (plasma creatinine below levels of the order of 25 mg/L, i.e. 220 micromole/L in an adult). In the elderly, this plasma creatinine must be adjusted in relation to age, weight and gender.
Hypovolaemia, secondary to the loss of water and sodium induced by the diuretic at the start of treatment causes a reduction in glomerular filtration. This may lead to an increase in blood urea and plasma creatinine. This transitory functional renal insufficiency is of no consequence in individuals with normal renal function but may worsen pre-existing renal insufficiency.

Athletes:
The attention of athletes is drawn to the fact that this medicinal product contains a drug substance, which may give a positive reaction in doping tests.

Choroidal effusion, acute myopia and secondary angle-closure glaucoma:
Sulphonamide, or sulphonamide derivative medicines, can cause an idiosyncratic reaction resulting in choroidal effusion with visual field defect, transient myopia and acute angle-closure glaucoma. Symptoms include acute onset of decreased visual acuity or ocular pain and typically occur within hours to weeks of drug initiation. Untreated acute angle-closure glaucoma can lead to permanent vision loss. The primary treatment is to discontinue medicine intake as rapidly as possible. Prompt medical or surgical treatments may need to be considered if the intraocular pressure remains uncontrolled. Risk factors for developing acute angle-closure glaucoma may include a history of sulphonamide or penicillin allergy.

Excipients:
INDAPAMIDE 1,5 mg SR PD contains sugar (lactose monohydrate 97,58 mg per tablet).
Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take INDAPAMIDE 1,5 mg SR PD.

Paediatric population
Children: Safety and efficacy have not been established, and INDAPAMIDE 1,5 mg SR PD is not recommended for use in children (see section 4.2).

4.5 Interaction with other medicines and other forms of interaction
Combinations that are not recommended:
Lithium
Increased plasma lithium with signs of overdosage, as with a salt-free diet (decreased urinary lithium excretion). However, if the use of diuretics is necessary, careful monitoring of plasma lithium and dose adjustment are required.

Combinations requiring precautions for use:
Torsade de pointes-inducing medicines
- class Ia antiarrhythmics (quinidine, hydroquinidine, disopyramide),
- class III antiarrhythmics (amiodarone, sotalol, dofetilide, ibutilide),
- some antipsychotics: phenothiazines (chlorpromazine, cyamemazine, levomepromazine, thioridazine, trifluoperazine), benzamides (amisulpride, sulpride, sultopride, tiapride) and butyrophenones (droperidol, haloperidol)
- others: bepridil, cisapride, diphemanil, erythromycin IV, halofantrine, mizolastine, pentamidine, sparfloxacin, moxifloxacin, vincamine IV.

Increased risk of ventricular arrhythmias, particularly torsade de pointes (hypokalaemia is a risk factor).
Monitor for hypokalaemia and correct, if required, before introducing this combination.
Clinical, plasma electrolytes and ECG monitoring.
Use substances which do not have the disadvantage of causing torsade de pointes in the presence of hypokalaemia.

Nonsteroidal anti-inflammatory medicines (NSAIDs) (systemic route) including COX-2 selective inhibitors, high dose salicylic acid (≥ 3 g/day)
Possible reduction in the antihypertensive effect of indapamide.
Risk of acute renal failure in dehydrated patients (decreased glomerular filtration). Hydrate the patient; monitor renal function at the start of treatment.

Angiotensin converting enzyme (ACE) inhibitors
Risk of sudden hypotension and/or acute renal failure when treatment with an ACE inhibitor is initiated in the presence of pre-existing sodium depletion (particularly in patients with renal artery stenosis).

In hypertension, when prior diuretic treatment may have caused sodium depletion, it is necessary:
- either to stop the diuretic 3 days before starting treatment with the ACE inhibitor, and restart with a hypokalaemic diuretic if necessary;
- or give a low initial dose of the ACE inhibitor and increase the dose gradually.

In congestive heart failure, start with a very low dose of ACE inhibitor, possibly after a reduction in the dose of the concomitant hypokalaemic diuretic.
In all cases, monitor renal function (plasma creatinine) during the first weeks of treatment with an ACE inhibitor.

Other compounds causing hypokalaemia: amphotericin B (IV), gluco- and mineralo-corticoids (systemic route), tetracosactide, stimulant laxatives
Increased risk of hypokalaemia (additive effect).
Monitoring of plasma potassium and correction if required. Must be particularly borne in mind in the case of concomitant digoxin treatment and in the use of non-stimulant laxatives.

Baclofen
Increased antihypertensive effect.
Hydrate the patient; monitor renal function at the start of treatment.

Digoxin
Hypokalaemia predisposing to the toxic effects of digoxin.
Monitoring of plasma potassium and ECG and, if necessary, adjust the treatment.

Combinations requiring special care:
Allopurinol
Concomitant treatment with indapamide may increase the incidence of hypersensitivity reactions to allopurinol.

Combinations to be taken into consideration:
Potassium-sparing diuretics (amiloride, spironolactone, triamterene)
Whilst rational combinations are useful in some patients, hypokalaemia or hyperkalaemia (particularly in patients with renal failure or diabetes) may still occur. Plasma potassium and ECG should be monitored and, if necessary, treatment reviewed.

Metformin
Increased risk of metformin induced lactic acidosis due to the possibility of functional renal failure associated with diuretics and more particularly with loop diuretics. Do not use metformin when plasma creatinine exceeds 15 mg/L (135 micromole/L) in men and 12 mg/L (110 micromole/L) in women.

Iodinated contrast media
In the presence of dehydration caused by diuretics, increased risk of acute renal failure, in particular when large doses of iodinated contrast media are used. Rehydration before administration of the iodinated compound.

Imipramine-like antidepressants, neuroleptics
Antihypertensive effect and increased risk of orthostatic hypotension increased (additive effect).

Calcium (salts)
Risk of hypercalcaemia resulting from decreased urinary elimination of calcium.

Ciclosporin, tacrolimus
Risk of increased plasma creatinine without any change in circulating cyclosporin levels, even in the absence of water/sodium depletion.

Corticosteroids, tetracosactide (systemic route)
Decreased antihypertensive effect (water/sodium retention due to corticosteroids).

Paediatric population
Children: Safety and efficacy have not been established, and INDAPAMIDE 1,5 mg SR PD is not recommended for use in children.

4.6 Fertility, pregnancy and lactation
Women of childbearing potential/contraception in males and females
Reproductive toxicity studies showed no effect on fertility in female and male rats (see section 5.3). No effects on human fertility are anticipated.

Pregnancy
INDAPAMIDE 1,5 mg SR PD should be avoided in pregnant women and should never be used to treat physiological oedema of pregnancy. Diuretics can cause foeto-placental ischaemia, with a risk of impaired foetal growth.

Breastfeeding
INDAPAMIDE 1,5 mg SR PD treatment is not recommended during breastfeeding. There is insufficient information on the excretion of indapamide/metabolites in human milk. Hypersensitivity to sulphonamide-derived medicines and hypokalaemia might occur. A risk to the newborns/infants cannot be excluded.
Indapamide is closely related to thiazide diuretics which have been associated with decrease or even suppression of milk lactation, during breastfeeding.

Fertility
Reproductive toxicity studies showed no effect on fertility in female and male rats. No effects on human fertility are anticipated.

4.7 Effects on ability to drive and use machines
INDAPAMIDE 1,5 mg SR PD does not affect alertness but different reactions in relation to the decrease in blood pressure may occur in individual cases, especially at the start of the treatment or when another antihypertensive agent is added.
As a result, the ability to drive vehicles or to operate machinery may be impaired.

4.8 Undesirable effects
a. Summary of the safety profile
The most commonly reported adverse reactions are hypersensitivity reactions, mainly dermatological, in subjects with a predisposition to allergic and asthmatic reactions and maculopapular rashes.
During clinical trials, hypokalaemia (plasma potassium <3,4 mmol/L) was seen in 10 % of patients and < 3.2 mmol/L in 4 % of patients after 4 - 6 weeks treatment. After 12 weeks treatment, the mean fall in plasma potassium was 0,23 mmol/L.
The majority of adverse reactions concerning clinical or laboratory parameters are dose-dependent.

b. Tabulated list of adverse effects

System Organ Class	Frequency	Side effects
Blood and lymphatic system disorders	*Less frequent*	Thrombocytopaenia, granulocytopaenia, leukopenia, aplastic anaemia, haemolytic anaemia, hypochloraemic alkalosis, hyponatraemia, hypokalaemia, hyperuricaemia
Immune system disorders	*Less frequent*	Skin rash, itching, pulmonary oedema, pneumonitis, cholestatic jaundice
Metabolism and nutrition disorders	*Less frequent* *Frequency unknown*	Hypercalcaemia Potassium depletion with hypokalaemia, particularly serious in certain high-risk populations (see section 4.4) hyponatraemia (see section 4.4)
Nervous system disorders	*Less frequent* *Frequency unknown*	Headaches, postural hypotension (dizziness especially when standing up from lying or sitting position), fatigue, paraesthesia Syncope
Eye disorders	*Frequency unknown*	Myopia, blurred vision, visual impairment, choroidal effusion
Cardiac disorders	*Less frequent* *Frequency unknown*	Arrhythmia *Torsade de pointes* (potentially fatal) (see sections 4.4 and 4.5)
Vascular disorders	*Less frequent*	Hypotension
Gastrointestinal disorders	*Less frequent*	Anorexia, gastric irritation, nausea, vomiting, constipation, diarrhoea, dry mouth, pancreatitis
Hepatobiliary disorders	*Less frequent* *Frequency unknown*	Abnormal hepatic function Possibility of onset of hepatic encephalopathy in case of hepatic insufficiency (see sections 4.3 and 4.4), hepatitis
Skin and subcutaneous tissue disorders	*Frequent* *Less frequent* *Frequency unknown*	Hypersensitivity reactions, maculopapular rashes Purpura, angioedema, urticaria, toxic epidermic necrolysis, Stevens-Johnson syndrome Possible worsening of pre-existing acute disseminated lupus erythematosus, photosensitivity reactions (see section 4.4)
Musculoskeletal, connective tissue and bone disorders	*Frequency unknown*	Muscle spasms, muscular weakness, myalgia, rhabdomyolysis
Renal and urinary disorders	*Less frequent*	Renal failure
Reproductive system and breast disorders	*Less frequent*	Erectile dysfunction
Investigations	*Frequency unknown*	Electrocardiogram QT prolonged (see sections 4.4 and 4.5), blood glucose increased (see section 4.4), blood uric acid increased (see section 4.4), elevated liver enzyme levels

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (MedsafetyX SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. An email can be sent directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product

4.9 Overdose
Indapamide has been found free of toxicity at up to 40 mg. This is 27 times the therapeutic dose.

Signs and symptoms:
Signs of acute poisoning take the form above all of water/electrolyte disturbances (hyponatraemia, hypokalaemia). Clinically, possibility of nausea, vomiting, hypotension, cramps, vertigo, drowsiness, confusion, polyuria or oliguria possibly to the point of anuria (by hypovolaemia).

Management of overdose:
Initial measures involve the rapid elimination of the ingested substance(s) by gastric wash-out and/or administration of activated charcoal, followed by restoration of water/electrolyte balance to normal in a specialised centre.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Sulphonamides, plain
ATC code: C03BA11
Pharmacological classification: A 7.1 Vasodilators, hypotensives, antihypertensive medicines.

Mechanism of action
Indapamide, [N-(3-sulphamoyl-4-chlorobenzamido) 2-methyl indoline], exhibits an antihypertensive action and falls in the chemical indole type of chlorosulphonamide. The antihypertensive effect of indapamide is due to the reduction in the total peripheral and arterial vascular resistance and possibly involves both renal and extra-renal effects. The diuretic effect (reduction of extra-cellular and blood volume) is believed to contribute minimally as decreases in blood pressure occur at doses well below the effective diuretic dose of indapamide. Hypertensive patients on long term indapamide treatment experience a reduction in left ventricular mass.
The elimination half-life is 14 -18 hours. Indapamide has a high plasma protein binding between 71 % and 79 %. The methyl-indoline portion of the molecule gives indapamide its lipophilic character, and indapamide's lipid solubility is 5 - 8 times that of the thiazides. As a result of this characteristic, indapamide further binds to elastin in vascular smooth muscle.

5.2 Pharmacokinetic properties
INDAPAMIDE 1,5 mg SR PD is supplied in a sustained release dosage based on a matrix system in which indapamide is dispersed within a support which allows sustained release of indapamide.

Absorption:
The fraction of indapamide released is rapidly and totally absorbed via the gastrointestinal digestive tract.
Eating slightly increases the rapidity of absorption but has no influence on the amount of the medicine absorbed.
Indapamide is completely absorbed reaching peak serum concentration within 12 hours, repeated administration reduces the variation in serum levels between 2 doses. Intra-individual variability exists.

Distribution:
Binding of indapamide to plasma proteins is 79 %. The plasma elimination half-life is 14 - 24 hours (mean 18 hours). Steady state is achieved after 7 days. Repeated administration does not lead to accumulation.

Biotransformation:
Indapamide is extensively metabolised in the liver and primarily renally excreted (60 - 70 %), with only 5 - 7 % found unchanged in the urine.

Elimination:
The excretion of indapamide further involves the faeces (16 - 23 %).

Pharmacokinetics in special patient groups
High risk individuals:
Pharmacokinetic parameters are unchanged in renal failure patients.

Paediatric population
Children: Safety and efficacy have not been established and INDAPAMIDE 1,5 mg SR PD is not recommended for use in children.

5.3 Preclinical safety data
Indapamide has been tested negative concerning mutagenic and carcinogenic properties.
The highest doses administered orally to different animal species (40 - 8000 times the therapeutic dose) have shown an exacerbation of the diuretic properties of indapamide. The major symptoms of poisoning during acute toxicity studies with indapamide administered intravenously or intraperitoneally were related to the pharmacological action of indapamide, i.e. bradypnoea and peripheral vasodilation. Reproductive toxicity studies have not shown embryotoxicity and teratogenicity. Fertility was not impaired either in male or in female rats.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Tablet cores:
Cellactose (a combination of alpha-lactose monohydrate and cellulose powder)
Hypromellose
Silica, colloidal anhydrous
Magnesium stearate

Film coating agent:
Opadry Y-1-7000 (a combination of hypromellose, macrogol 400 and titanium dioxide).

6.2 Incompatibilities
Not applicable

6.3 Shelf life
3 years.

6.4 Special precautions for storage
Store at or below 30 °C.
Do not remove the blisters from the outer carton until required for use.

6.5 Nature and contents of container
INDAPAMIDE 1,5 mg SR PD tablets are packed in aluminium foil and transparent, hard PVC/PVDC foil blister strips, with 30 tablets inside an outer carton box.

6.6 Special precautions for disposal
No special requirements

7. HOLDER OF CERTIFICATE OF REGISTRATION
Pharma Dynamics (Pty) Ltd
1st Floor Grapevine House, Steenberg Office Park
Silverwood Close
Westlake, 7945
Cape Town, South Africa
Tel: + 27 21 707 7000
or 0860-PHARMA (742 762)

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A42/7.1/0790

9. DATE OF FIRST AUTHORISATION
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pharma dynamics

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 97,58 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
2. What you need to know before you take INDAPAMIDE 1,5 mg SR PD
3. How to take INDAPAMIDE 1,5 mg SR PD
4. Possible side effect
5. How to store INDAPAMIDE 1,5 mg SR PD
6. Contents of the pack and other information

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 offer 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 Other medicines and INDAPAMIDE 1,5 mg SR PD)
- 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, total lactase deficiency or glucose-galactose malabsorption, you should not take INDAPAMIDE 1,5 mg SR PD.
- if you are an athlete, you must be aware of the fact that INDAPAMIDE 1,5 mg SR PD 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, sulpride, 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)
- Nonsteroidal 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 taking
INDAPAMIDE 1,5 mg SR PD.
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 effects 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 INDAPAMIDE 1,5 mg SR PD.

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 are not 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), 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), leukopenia (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 characterised by low body weight), stomach pain, gas and bloatedness, nausea, vomiting, constipation, diarrhoea, dry mouth
- discoloration 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 (MedsafetyX SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website https://www.safpra.org.za/Publications/Index/6
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
Tablet cores: cellacotse (a combination of alpha-lactose monohydrateband cellulose powder), hypromellose, magnesium stearate, silica (colloidal anhydrous).

Film coating agent: opadry Y-1-7000 (a combination of hypromellose, macrogol 400 and titanium dioxide).

What INDAPAMIDE 1,5 mg SR PD looks like and contents of the pack
INDAPAMIDE 1,5 mg SR PD tablets are white, round, slightly biconvex film coated tablets. It is packed in aluminium foil and transparent, hard PVC/PVDC foil blister strips, with 30 tablets inside an outer carton box.

Holder of Certificate of Registration
Pharma Dynamics (Pty) Ltd
1st Floor Grapevine House, Steenberg Office Park
Silverwood Close
Westlake, 7945
Cape Town, South Africa
Tel: + 27 21 707 7000
or 0860-PHARMA (742 762)

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PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S3

INDAPAMIDE 1,5 mg SR PD
Volgehouervrystelling-tablet
Indapamide
INDAPAMIDE 1,5 mg SR PD bevat suiker (laktosemonohidraat 97,58 mg per tablet).

Lees hierdie hele inligtingsblad noukeurig deur, voordat u begin om INDAPAMIDE 1,5 mg SR PD te gebruik
- Hou hierdie inligtingsblad. Dit mag nodig wees vir u om dit weer te lees.
- Indien u verdere vrae het, vra asseblief u dokter, apteker, verpleegkundige, of ander gesondheidsorgwerksaffer.
- INDAPAMIDE 1,5 mg SR PD is vir u persoonlik voorgeskryf en u moet nie u medisyne met ander mense deel nie. Dit mag skadelik wees vir hulle, selfs al is hulle simptome dieselfde as u eie.

Inhoud van hierdie inligtingsblad
1. Wat INDAPAMIDE 1,5 mg SR PD is en waarvoor dit gebruik word
2. Wat u nodig het om te weet, voordat u INDAPAMIDE 1,5 mg SR PD gebruik
3. Hoe om INDAPAMIDE 1,5 mg SR PD te neem
4. Moontlike newe-effekte
5. Hoe om INDAPAMIDE 1,5 mg SR PD te bewaar
6. Verpakkingsinhoud en ander inligting

1. Wat INDAPAMIDE 1,5 mg SR PD is en waarvoor dit gebruik word
INDAPAMIDE 1,5 mg SR PD bevat indapamiel, een van 'n groep medisyne, wat vatverwyders genoem word.

INDAPAMIDE 1,5 mg SR PD word deur dokters voorgeskryf, om hoë bloeddruk te behandel.

2. Wat u nodig het om te weet, voordat u INDAPAMIDE 1,5 SR PD gebruik
Moet nie INDAPAMIDE 1,5 mg SR PD neem:
- indien u allergies (hipersensitief) is vir indapamiel, ander sulfonamiel-tipe medikasie (ook sulfa-medikasie genoem en gebruik word vir die behandeling van verskillende infeksies), of vir enige van die ander bestandele van INDAPAMIDE 1,5 mg SR PD, nie (sien afdeling 6)
  Raadpleeg asseblief u dokter, indien u allergies is vir sulfonamiel-tipe medisyne (sulfa-medikasie), veral indien u voorheen voorvalle van allergiese reaksies gehad het, nadat u hierdie medisyne ontvang het
- indien u erge lewersiekte het, of aan 'n toestand lê wat hepatiese enkefalopatie genoem word nie (degenerasiewe breinsiekte)
- indien u erge nierversaking het nie
- indien u lae kaliumvlakke in u bloed het nie.

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met INDAPAMIDE 1,5 mg SR PD:
- indien u bejaard is, aangesien u meer sensitief vir die elektroliet- en bloeddrukverlagende werking van INDAPAMIDE 1,5 mg SR PD mag wees
- indien u nierskade het, of nie in staat is om te urineer nie
- indien u diabetes het, is dit belangrik dat u bloedglukose (bloedsuiker) gemoniter word, in die aanwesigheid van hipokalemie
- indien u aan jig ly, wat mag vererger, wees verhoging van urienssuurvlakke in u bloed
- indien u enige skade aan u lewer het, wat lei tot verlies van lewerfunksie
- indien u 'n simpatektomie gehad het (operasie om die sentrale senuwee in die liggaam te blokkeer, en toestande soos ultermatige gesweet, of erge gesigsblosverroming/blosing, te behandel)
- indien u 'n elektrolietwanbalans het, weens dehidrasie. U dokter mag toetse aanvra, om iae natrium-, magnesium-, of kaliumvlakke, of hoë kalsiumvlakke te bepaal
- indien u 'n onreëlmatige hartritmebeestand het
- indien u ander diuretika neem, terwyl u INDAPAMIDE 1,5 mg SR PD gebruik, mag dit hipokalemie veroorsaak en word nie aanbeveel nie (sien Ander medisyne en INDAPAMIDE 1,5 mg SR PD)
- indien u lewer nie behoorlik funksioneer nie, moet INDAPAMIDE 1,5 mg SR PD nie geneem word nie
- indien u 'n fotosensitiwiteitsreaksie ervaar, terwyl u INDAPAMIDE 1,5 mg SR PD gebruik. Indien u aanhou om die medikasie te gebruik, word daar aanbeveel dat blootgestelde veloppervlakkes teen die son, of kunsmatige UVA, beskerm word
- indien u aan skaars oorerflike probleme van galaktose onverdragsaamheid, algehele laktase tekort, of glukose-galaktose waroborpsie ly, moet u nie INDAPAMIDE 1,5 mg SR PD
- indien u 'n atleet is, moet u bewus wees van die feit dat INDAPAMIDE 1,5 mg SR PD 'n bestandeel bevat, wat 'n positiewe reaksie tydens dwelmtoetse mag oplewer
- indien u 'n afname in sig, of oogpyn ervaar. Hierdie mag simptome van vloeistof-sekumulasie in die vaskulêre laag van die oog wees (choroidale effusie), of 'n verhoging in oogdruk. Dit kan voorkom binne ure tot en met weke nadat u INDAPAMIDE 1,5 mg SR PD geneem het.

Kinders en adolessente:
Kinders: Veiligheid en doeltreffendheid is nie vasgestel nie en INDAPAMIDE 1,5 mg SR PD word nie aanbeveel vir gebruik deur kinders nie.

Ander medisyne en INDAPAMIDE 1,5 mg SR PD
Vertel altyd u gesondheidsorgwerksaffer indien u enige ander medisyne neem. Hierdie sluit aanvullende, of tradisionele medisyne in.
- litium (gebruik om depressie te behandel), weens 'n verhoging van litiumvlakke in die bloed
- die volgende medisyne, indien dit saam met INDAPAMIDE 1,5 mg SR PD gebruik word, mag ernstige abnormale hartritme veroorsaak:
  - medikasie vir hartritmeprobleme (bv. kinidien, hidrokinidien, disopiramiel, amiodaron, sotalol, ibutilied, dofetilied)
  - medikasie wat gebruik word om geestesversteurings, soos depressie, angstsiekeid en sikosfrenie te behandel, sommige antipsigotika: fenotiasiene (chloorpromaisen, siamemasien, levopromasien, foridasien, trifluoperasien), benzamiede (amisulpried, sulpried, sultopried, tapried), butirofenone (droperidol, haloperidol)
  - ander medisyne – bepridil (om angina te behandel), sisapried (om gastriese refluks te behandel), difemaniel (behandel ultermatige gesweet), antibiotika (eritromisien IV, sparfloksasien en moksifloksasien), halofantrien (om malaria te behandel), misolastien (anti-allergie medisyne), pentamidien (om pneumonie te behandel), vinkamien IV (om hoë bloeddruk te behandel)
- niesteroïdale anti-inflammatoriese medisynes vir pynverlighting (bv. ibuprofen), of hoë dosisse aspirien, mag die effek van INDAPAMIDE 1,5 mg SR PD verswak
- angiotensienomsettingsensiem (AOE) inhibitors, bv. enalapril, ramipril (gebruik om hoë bloeddruk en hartversaking te behandel), mag die werking van INDAPAMIDE 1,5 mg SR PD, versterk
- stimulantlakseermiddels, soos senna en bisokodiel (gebruik om darmbeweging aan te moedig)
- baklofen (om spierstyfheid, wat met siektes soos veelvoudige sklerose voorkom, te behandel), mag die werking van INDAPAMIDE 1,5 mg SR PD, versterk
- allopurinol (vir die behandeling van jig), aangesien hipersensitiwiteit/allergiese reaksies mag toeneem
- digoksien (om angina te behandel) – toksiese effekte mag toeneem
- kaliumsparende diuretika – wattertablette (amiloried, spironolakloon, triamteren)
- metformien (gebruik om diabetes te behandel), lei tot 'n toenemende risiko vir laktiese asidose (te veel melksuur in die liggaam), met simptome soos maagongemak, spierpyn, spierkramp, ongewone moegheid, of swakheid
- gejodeerde kontrasmedium (gebruik vir toetse wat X-strale behels), verhoog die risiko vir niersiekte
- imipramien (om depressie te behandel), mag die risiko vir lae bloeddruk verhoog, wanneer u vanuit 'n liende, of sittende posisie opstaan
- kalsiumtablette, of ander kalsiumaanvullings, mag die kalsiumvlakke in die bloed verhoog
- siklosporien, takrolimus, of ander medisyne wat die immuunstelsel, na 'n orgaanoorplanting onderdruk, om 'n outo-immuursiekte, of erge rumatiek, of dermatologiese siektes, te behandel
- kortikosteroïede, tetrakosiksiel, verswak die werking van INDAPAMIDE 1,5 mg SR PD.

INDAPAMIDE 1,5 mg SR PD saam met kos, drinkgoed en alkohol
INDAPAMIDE 1,5 mg SR PD kan saam met, of sonder kos geneem word.

Swangerskap, borsvoeding en fertiliteit
Indien u swanger is, of u baba borsvoed, vermoed dat u swanger is, of 'n baba beplan, raadpleeg asseblief u dokter, apteker, of ander gesondheidsorgwerksaffer vir advies, voordat u INDAPAMIDE 1,5 mg SR PD neem
MOET NIE INDAPAMIDE 1,5 mg SR PD gebruik indien u swanger is, of vermoed dat u swanger is nie.
Kontak u dokter onmiddellik.
MOET NIE INDAPAMIDE 1,5 mg SR PD neem indien u borsvoed nie.

Bestuur en die hantering van masjiene
INDAPAMIDE 1,5 mg SR PD kan newe-effekte veroorsaak, weens die verlaging van bloeddruk, soos duiselighed of moegheid (sien afdeling 4). Hierdie newe-effekte kom meer algemeen voor met die aanvang van behandeling en na dosisverhogings. Indien dit sou voorkom, vermy bestuur en ander aktiwiteite wat u aandag vereis. Onder goeie beheer, is dit egter onwaarskynlik dat hierdie newe-effekte voorkom.

Dit is nie altyd moontlik om te voorspel tot watter mate INDAPAMIDE 1,5 mg SR PD met die daaglikse aktiwiteite van 'n pasiënt sal inmeng nie. Pasiënte moet verseker dat hulle nie by bogenoemde aktiwiteite betrokke raak, totdat hulle weet tot watter mate INDAPAMIDE 1,5 mg SR PD, hulle beïnvloed nie.

INDAPAMIDE 1,5 mg SR PD bevat laktosemonohidraat
Indien u dokter aangedui het, dat u 'n onverdragsaamheid teenoor sommige suikers toon, kontak u dokter, voordat u INDAPAMIDE 1,5 mg SR PD neem.

3. Hoe om INDAPAMIDE 1,5 mg SR PD te gebruik
Moet nie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie.
Neem INDAPAMIDE 1,5 mg SR PD altyd presies soos deur u dokter aanbeveel word. Raadpleeg u dokter, of apteker indien u onseker is.

Volwassenes:
Die gewone dosis is een INDAPAMIDE 1,5 mg SR PD tablet elke dag, verkieslik wanneer u soggens opstaan.

Die tablet moet heel, verkieslik wanneer u soggens wakker word, met water geslok word, en nie gekou word nie.

U dokter sal u vertel vir hoe lank u behandeling met INDAPAMIDE 1,5 mg SR PD sal duur.
Indien u onder die indruk is, dat die werking van INDAPAMIDE 1,5 mg SR PD te sterk, of te swak is, praat met u dokter, of apteker.

Indien u meer INDAPAMIDE 1,5 mg SR PD neem as wat u moes:
In die geval van oordosering, raadpleeg u dokter, of apteker. Indien beide nie beskikbaar is nie, kontak u naaste hospitaal, of giftheeresentrum.

Simptome van oordosering mag die volgende insluit:
- water/elektrolietversteurings, naarheid, braking, lae bloeddruk, krampe, vertigo, lomerigheid, verwarring, toename in urinering, afname in urinering, poliurie, of oliguria, moontlik tot die punt van anurie (wanneer die niere nie genoeg urine vervaardig nie).

Indien u vergeet om INDAPAMIDE 1,5 mg SR PD te neem
Indien u vergeet om INDAPAMIDE 1,5 mg SR PD te neem, neem die volgende dosis so gou as wat u onthou. Gaan dan voort om INDAPAMIDE 1,5 mg SR PD op die vasgestelde tye te neem. Moet nie 'n dubbeldosis neem, om op te maak vir die vergete, individuele doserings nie.

Indien u die gebruik van INDAPAMIDE 1,5 mg SR PD staak
Die behandeling van hoë bloeddruk is gewoonlik lewenslank en u moet u dokter raadpleeg, voordat hierdie medikasie gestaak word.

4. Moontlike newe-effekte
INDAPAMIDE 1,5 mg SR PD kan newe-effekte hê.
Nie alle newe-effekte wat vir INDAPAMIDE 1,5 mg SR PD aangemeld is, word in hierdie inligtingsblad ingesluit nie. Sou u algemene gesondheid verslec, of indien u enige ongunstige effekte ervaar terwyl u INDAPAMIDE 1,5 mg SR PD gebruik, raadpleeg asseblief u dokter, apteker, of ander gesondheidsorgdeskundige vir advies.

Indien enige van die volgende gebeur, staak die gebruik van INDAPAMIDE 1,5 mg SR PD en vertel u dokter onmiddellik, of gaan na die ongevalle-afdeling by u naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe, mond, of keel, wat sluk, of asemhaling mag bemoeilik
- uitslag, of gejeuk
- floute.

Hierdie is alles baie ernstige newe-effekte. Indien u dit ervaar, kan u 'n ernstige allergiese reaksie teenoor INDAPAMIDE 1,5 mg SR PD ondervind het. U mag dringende mediese aandag, of hospitalisasie benodig.

Vertel u dokter onmiddellik, of gaan na die ongevalle-afdeling by u naaste hospitaal, indien u enige van die volgende opmerk:
- moeisame asemhaling, asemnood, stywe gevoel in die bors
- abnormale hartritme, wat mag lei tot skielike hartsterfte
- verminderde lewerfunksie, met simptome soos, buikpyn, of swelling, geelsug, naarheid en braking, diagnose van hepatitis (virusinfeksie van die lewer), cholestatiese geelsug (simptome wat vergeling van die vel, of oë insluit)
- toksiese epidermale nekrolise en Stevens-Johnson-sindroom (koors en koors-soortige simptome, 'n plat rooi uitslag, gevolg deur weltjiese en afskilfering en blase en sere op die slymvliesmembrane)
- nierversaking (simptome sluit aptyfverlies en uitputting in)
- pankreatitis (inflammasie van die pankreas met simptome wat erge buik- en rugpyn insluit en ook geparadigsan met 'n gevoel van erge ongestelldheid
- breinsiekte, wat veroorsaak word deur lewersiekte (hepatiese enseflalopatie), met simptome wat verwarring, uitputting, flapperende handtremor, slaperigheid, slegte asem van lewersiekte, prikkelbaarheid, geheueverlies, of sleperide spraak, mag insluit
- afname in sig, of pyn in die oë, weens hoë druk (moontlike tekens van vloeistofskumulasie in die vaskulêre lag van die oog (choroidale effusie)
- rabdomiolise ('n ernstige mediese toestand wat moeilottig mag wees, of mag lei tot permanente ongeskiktheid. Simptome sluit spierkramp, skete of pyne wat erger voorkom as wat verwag word, donker urine (tee- of kola-kleurig), voel swak of moeg, nie staat om take, of 'n oefeningsroetine te voltooi nie), in. Hierdie is alles ernstige newe-effekte. U mag dringende mediese aandag benodig.

Vertel u dokter, indien u enige van die volgende opmerk: Newe-effekte wat dikwels voorkom:
- beide plat en verhewe "sweiseis" op die vel.

Newe-effekte wat minder dikwels voorkom:
- abnormale bloedtellings, anemie, neiging om maklik te bloei, veranderinge in bloedselle, soos trombosiitopenie (afname in die hoeveelheid bloedplatjies, wat maklike bloeding tot gevolg het en neusbloeding), leukopenie (afname in witbloedselle, wat onverklaarbare koors, keelsere, of ander grip-soortige simptome tot gevolg mag hê – indien dit voorkom, raadpleeg u dokter)
- hoofpyne, duiselighed, (veral wanneer u opstaan vanuit 'n liende, of sittende posisie), moegheid, "spelde en naalde" gevoel op die vel
- lae bloeddruk
- anorekse (eetversteuring, gekenmerk deur lae liggaamsgewig), maagpyn, winderigheid en opgeblase gevoel, naarheid, braking, hardlywigheid, diarree, droë mond, pankreatitis, (inflammasie van die pankreas)
- verkleuring van die vel, wat gevorm word deur klein bloeiende bloedvate, urtikaria, of galbulte ('n tipe velutslag, met rooi, geswelde, jeukerige knoppe)
- erektiele disfunksie.

Die volgende newe-effekte is aangemeld, maar die frekwensie van voorkoms, is onbekend:
- elektrolietwanbalans – natrium, kalium (simptome soos moegheid en beenkramp), kalisum
- kortsigtigheid, versteurde visie, sigverlies
- moontlike agteruitgang van voorafbestaande akute gedissemineerde lupus erythematosus (versameling van outo-immuunsiektes, waar die immuunstelsel, gesonde weefsel aanval), fotosensitiwiteitsreaksie ('n uiterste sensitiwiteit vir ultraviolet (UV) strale van die son en ander ligbronne)
- abnormale elektrokardiogram (toon die hartklopgatroon), bloedtoetsresultate, wat 'n verhoging in glukose/suikervlakke, uriensuur- en lewerensiemvlakke toon
- spierswakheid, spasmas, of pyn.

Indien u enige newe-effekte opmerk, wat nie in hierdie inligtingsblad genoem word nie, lig asseblief u dokter, of apteker in.

Aanmeldingvan newe-effekte
Indien u newe-effekte ervaar, praat met u dokter, apteker of verpleegkundige. U kan ook newe-effekte aanmeld by SAHPRA via die Med Safety toepassing (MedsafetyX SAHPRA) en eReporting platform (who-umc.org), wat op SAHPRA se webtuiste gevind kan word.
Deur die aanmelding van newe-effekte, kan u help om meer inligting aangaande die veiligheid van INDAPAMIDE 1,5 mg SR PD in te win. U kan ook 'n epos direk na die maatskappy stuur, pharmacovigilance@pharmadynamics.co.za om veiligheid van die produk te verseker.

5. Hoe om INDAPAMIDE 1,5 mg SR PD te bewaar
Bewaar alle medisyne buite die bereik van kinders.
Bewaar teen of benede 30 °C in die oorspronklike houer.
Moet nie stukstroke vanuit die buitenste kartonhouer verwyder, totdat dit benodig word gebruik nie
Moet nie gebruik na die vervaldatum wat op die kartonhouer gedruk is nie.
Neem alle ongebruikte medisyne na u apteker terug.
Moet nie ongebruikte medisyne in afvoerpype, of rioolsteels (bv. toilette), weggooi nie.

6. Verpakkingsinhoud en ander inligting
Wat INDAPAMIDE 1,5 mg SR PD bevat:
Die aktiewe bestanddeel is indapamiel.
Elke tabletbevat 1,5 mg indapamiel.

Die ander bestandele is
Tablet kerne: hipromellose, magnesiumstearaat, sellakitose ('n kombinasie van alfalaktosemonohidraat en sellulose poeier), silika (watervry kolloïdaal).

Foibedekking: Opadry Y-1-7000 ('n kombinasie van titaandioksied, hipromellose, makrogol 400 en titaandioksied).

Hoe INDAPAMIDE 1,5 mg SR PD lyk en die verpakkingsinhoud
INDAPAMIDE 1,5 mg SR PD tablette is wit, ronde, effens biconvekse filmbedekte tablette. Dit word verpak in aluminiumfoeile en deurskynende, harde PVC/PVDC foeile stulpstroke, met 30 tablette, binne-in 'n buitenste kartonhouer.

Eienaar van die Registrasiesertifikaat
Pharma Dynamics (Edms.) Bpk.
1ste Vloer Grapevine House, Steenberg Office Park
Silverwood Close
Westlake, 7945
Kaapstad, Suid-Afrika
Tel: + 27 21 707 7000
of 0860-PHARMA (742 762)

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