PACKAGE INSERT FOR DYNA INDAPAMIDE SR

SCHEDULING STATUS: S3

PROPRIETARY NAME AND DOSAGE FORM:

DYNA INDAPAMIDE SR sustained release tablets

COMPOSITION:

Each sustained release tablet contains 1,5 mg Indapamide.

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

PHARMACOLOGICAL CLASSIFICATION

A 7.1 Vasodilators, Hypotensive Medicine.

PHARMACOLOGICAL ACTION:

Pharmacodynamics:

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.

Pharmacokinetics:

Indapamide is completely absorbed reaching peak serum concentration within 12 hours. Indapamide is extensively metabolised in the liver and primarily renally excreted (60 to 70 %) with only 5-7 % is found unchanged in the urine. The excretion of indapamide further involves the faeces (16 to 23 %). 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 to 8 times that of the thiazides. As a result of this characteristic indapamide further binds to elastin in vascular smooth muscle.

INDICATIONS:

DYNA INDAPAMIDE SR is indicated in the management of mild to moderate hypertension.

CONTRA-INDICATIONS:

- Hypersensitivity to indapamide, other sulphonamide type medications, or any of the components of **DYNA INDAPAMIDE SR**.
- Severe hepatic impairment.
- Severe renal failure.
- Safety in pregnancy and lactation has not been established.

WARNINGS:

The elderly patient population may be more sensitive to the electrolyte and hypotensive effects of **DYNA INDAPAMIDE SR**. 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.

INTERACTIONS:

The following medicines may result in a interaction when given concomitantly with **DYNA INDAPAMIDE SR**:

- Amiodarone (increased risk of arrhythmias associated with hypokalaemia);
- Anticoagulants, coumarin- or indandione-derivative (effects may be decreased);
- Digitalis glycosides (enhance digitalis toxicity associated with hypokalaemia);
- Other antihypertensive agents;
- Lithium (enhance risk for lithium toxicity, due to decreased renal clearance);
- Neuromuscular blocking nondepolarising agents (enhance blockade);
- Sympathomimetics (reduce the effects of **DYNA INDAPAMIDE SR**).

PREGNANCY AND LACTATION:

There is no clinical experience with **DYNA INDAPAMIDE SR** in pregnancy and is therefore not recommended during pregnancy.

DYNA INDAPAMIDE SR treatment is not recommended during breastfeeding.

DOSAGE AND DIRECTIONS FOR USE:

Adults: One tablet daily, preferably taken on arising in the morning.

DYNA INDAPAMIDE SR (1,5 mg indapamide) can be combined with other categories of antihypertensive agents.

Geriatric patients may be more sensitive (see **WARNINGS**).

Children: Safety and efficacy has not been established and **DYNA INDAPAMIDE SR** is not recommended for use in children.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Side Effects:

Blood and lymphatic system disorders

Less frequent: Thrombocytopaenia, granulocytopaenia, leucopaenia, aplastic anaemia, haemolytic anaemia, hypochloraemic alkalosis, hyponatraemia, hypokalaemia, hyperuricaemia

Immune system disorders

Less frequent: Skin rash, itching, pulmonary oedema, pneumonitis, cholestatic jaundice, pancreatitis

Nervous system disorders

Less frequent: Headaches, postural hypotension (dizziness especially when standing up from lying or sitting position).

Gastrointestinal disorders

Less frequent: Anorexia, gastric irritation, nausea, vomiting, constipation, diarrhoea

Special Precautions:

Hypersensitivity to other sulphonamide-type medicines may lead to allergic reaction when taking **DYNA INDAPAMIDE SR**.

Laboratory test values that may be altered while taking **DYNA INDAPAMIDE SR** 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).

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

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 **DYNA INDAPAMIDE SR** with other diuretics, which may cause hypokalaemia, is not recommended (see **INTERACTIONS**).

DYNA INDAPAMIDE SR can be administered to hypertensive patients with mild to moderately impaired renal function. If azotaemia or oliguria occurs, the treatment should be discontinued.

Ability to drive or use machinery:

DYNA INDAPAMIDE SR does not affect alertness but different reactions in relation with 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.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Symptoms

(See **SIDE EFFECTS AND SPECIAL PRECAUTIONS**.)

Symptoms could include: allergies, skin rashes, epigastric pain, nausea, photosensitivity, dizziness, weakness and paraesthesia.

Treatment

DYNA INDAPAMIDE SR overdose should be treated by immediate evacuation of the stomach followed by supportive and symptomatic treatment. Electrolyte concentrations and renal function must be monitored.

STORAGE INSTRUCTIONS:

Store at or below 25 °C.

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

KEEP OUT OF REACH OF CHILDREN.