Please read this leaflet carefully before you start taking this medicine.

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor or your pharmacist.

This medicine 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.

SCHEDULING STATUS: S3

PROPRIETARY NAME AND DOSAGE FORM:

MYLAN INDAPAMIDE 2,5 mg (Tablet)

COMPOSITION OF THE MEDICINE, THAT IS, WHAT THIS MEDICINE CONTAINS:

Each tablet contains 2,5 milligrams of Indapamide hemihydrate, a thiazide diuretic.

The inactive ingredients in the tablets are lactose (anhydrous), microcrystalline cellulose, sodium starch glycolate, Croscarmelose sodium Type A, magnesium stearate.

INDICATIONS AND USE, THAT IS, WHAT THIS MEDICINE IS USED FOR:

MYLAN INDAPAMIDE 2,5 mg tablets are used for the treatment of:

- Mild to moderate hypertension. MYLAN INDAPAMIDE 2,5 mg may be used as sole (only) therapy or combined with non-thiazide antihypertensive medicines.

BEFORE TAKING THIS MEDICINE:

Please read this leaflet before you take your MYLAN INDAPAMIDE 2,5 mg tablets. This gives you important information about your tablets. Please keep this leaflet safe. You

may want to read it again. If you have any questions, or if you are not sure about anything, ask your doctor or pharmacist.

Do not take this medicine if you:

- Are hypersensitive to any of the ingredients of MYLAN INDAPAMIDE 2,5 mg.
- Are hypersensitive to sulphonamide derivatives.
- Had a recent cerebrovascular accident (stroke).
- Have severe impairment of hepatic function or severe renal insufficiency and hepatic encephalopathy.
- Suffer from hypokalaemia (abnormally small amounts of potassium in the circulationg blood).

PREGNANCY AND BREASTFEEDING:

MYLAN INDAPAMIDE 2,5 mg should also not be in used in patients who:

- Are pregnant, or think they might be as safety has not been established.

MYLAN INDAPAMIDE 2,5 mg should be used with caution in patients who:

- Have impaired liver function.
- Have kidney impairment.
- Have systemic lupus erythematosus because it may be exacerbated or activated in susceptible patients.
- Are being treated with coumarin anti-coagulants.
- The elderly.

Tell your doctor or pharmacist before taking this medicine if you are already taking any of the following medicines:

- Carbenoxolone or diuretics,cardiac glycosides, antiarrhythmics (eg quinidine derivatives), corticosteroids and laxatives. Hypokalaemia can occur if MYLAN INDAPAMIDE 2,5 mg is co-administered.
- Lithium.
- Medicines which may lead to torsades de pointes tachycardia:
  - antiarrhythmics, group Ia (quinidine)
  - antiarrhythmics, group III (amiodarone, sotalol)
  - Certain antipsychotics:
  - phenothiazines (chlorpromazine, levomepromazine)
  - amisulpride, sulpride
  - butyrophenones (droperidol, haloperidol)
  - Other: erythromycin IV, mizolastine, pentamidine, moxifloxacin

  Increased risk of ventricular arrhythmia, especially torsades des pointes (hypokalaemia is a predisposing factor). Plasma potassium should be monitored by your doctor, and if necessary corrected, before starting this medicine.

- Digoxin (hypokalaemia increases the sensitivity to digoxin).

  Systemic non-steroidal anti-inflammatory drugs; including COX-2 inhibitors, and large doses of acetylsalicylic acid.

- Angiotensin-converting enzyme (ACE) inhibitors (risk of acute hypotension and/or renal failure).
- Medicines which are predisposing factors of hypokalaemia (amphotericin B - iv), systemic glucocorticoids and mineral corticoids, tetracosactide (increased risk of hypokalaemia).
- Baclofen.
- Potassium saving diuretics (amiloride, spironolactone).
- Metformin (increased risk of lactic acidosis).
- Iodine-containing contrast media.
- Tricyclic antidepressants, antipsychotics.
- Ciclosporin, tacrolimus.

If you are taking medicines on a regular basis, concomitant use of the medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.

HOW TO TAKE THIS MEDICINE:

Treatment of adults:

Your treatment will normally be one (2,5 mg) tablet to be taken in the morning.

Treatment of the elderly:

The elimination time of MYLAN INDAPAMIDE 2,5 mg may be prolonged in older people, because they are more susceptible to electrolyte imbalance and fluid loss. Therefore, it is advisable to monitor these patients frequently for evidence of such effects.

Treatment of children:

Children must not use this medicine. There is insufficient experience of the use in children.

In the event of an overdosage, consult your doctor or pharmacist. If neither is available, rush the patient to the nearest hospital of poison control centre. Show the pack to the doctor.

Do not share medicines prescribed for you with others.

SIDE-EFFECTS:

Most people take this medicine without many side-effects, but all medicine can cause some side-effects.

Stop taking MYLAN INDAPAMIDE 2,5 mg and consult your doctor if they become troublesome, or the emergency room of the nearest hospital, if you experience the following:

- difficulty breathing or wheezing

These may be signs of an allergic reaction to MYLAN INDAPAMIDE 2,5 mg and you should contact your doctor immediately.

Other side-effects you may experience are as follows:

- dizziness
- fatigue
- headache
- nausea
- constipation
- dry mouth

- skin rash
- general feeling of being unwell

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

STORAGE AND DISPOSAL INFORMATION:

- Store your tablets in a dry place below 25 ºC.
- Do not take the tablets after the expiry date printed on the packet.
- If you don't need to take this medicine anymore, take it to your doctor or nearest pharmacy to dispose of it.

Store all medicine out of reach of children

These tablets are for you. Please do not give them to anyone else, even if they have the same symptoms as you.

PRESENTATION:

Securitainers or blister packs containing 30 or 300 tablets.

IDENTIFICATION OF THE MEDICINE:

White, round, biconvex, film-coated tablets.

REGISTRATION NUMBER:

29/7.1/0590

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Mylan (Pty) Ltd

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Emerald Boulevard

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South Africa

THE DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

27 June 2008