



INDAPAMIDE BEKER LP

1.5 mg Prolonged-release coated tablets,

1- FORM & PRESENTATION:

Indapamide BEKER® LP: Prolonged-release coated Tablets, Pack of 30 tablets.

2- COMPOSITION:

Each prolonged-release coated tablet contains:
Indapamide..... 1.5 mg/tab.

Excipients:

Lactose, hypromellose, colloidal anhydrous silica, magnesium stearate, titanium dioxide, polydextrose talc, maltodextrin, medium-chain triglycerides, yellow iron oxide, red iron oxide.

Excipient with known effect:

Lactose..... 120.9 mg/Cp

3- THERAPEUTIC CLASS:

Antihypertensive diuretic acting on the cortical diluting segment.

4- THERAPEUTIC INDICATIONS:

This medication is indicated for the treatment of essential hypertension in adults.

5- POSOLOGY AND METHOD OF ADMINISTRATION:

Posology:

One tablet every 24 hours, preferably in the morning, with or without food, given the diuretic effect of this medication to avoid possible nighttime awakenings. Higher doses do not improve the antihypertensive action of indapamide but do increase its saluretic effect (increases urinary water and sodium excretion).

Method of administration:

Oral use.
Swallow the tablet whole with water. Do not crush or chew the tablet.

ADHERE STRICTLY TO THE DOSAGE INDICATED BY YOUR DOCTOR

6- CONTRAINDICATIONS:

Do not take Indapamide BEKER® LP in the following cases:
-Hypersensitivity to the active substance, other sulfonamides, or any of the excipients of this medication.
-Renal failure.
-Hepatic encephalopathy (degenerative brain disease) or severe liver failure.
-Hypokalemia (abnormal decrease in blood potassium levels).

IF IN DOUBT, ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

7- SPECIAL WARNINGS AND PRECAUTIONS FOR USE:

Special Warnings:

The administration of this medicine must be stopped immediately in case of liver damage.

If a photosensitivity reaction (sun allergy) occurs during treatment, it is recommended to stop the treatment. If further administration of the diuretic becomes necessary, it is recommended to protect body parts exposed to the sun or UV light.

If your doctor informs you that you have an intolerance to certain sugars, contact him before taking this medication.

Precautions for Use:

Talk to your doctor before taking Indapamide BEKER® LP in the following cases:

- Fluid and electrolyte balance disorders (sodium, potassium, calcium or magnesium levels)
- Diabetes.
- Gout (a chronic disease linked to excess uric acid in the blood).
- Kidney problems.
- Liver problems and heart rhythm problems.
- If you experience decreased vision or eye pain.
- If you have muscle problems (pain, tenderness, weakness, or cramps).
- If you need to have your parathyroid gland tested.
- If you have had photosensitivity reactions.

*Your doctor may prescribe laboratory tests to monitor your treatment.

*Athletes should be aware that this product contains an active ingredient that may cause a positive reaction in tests performed during doping controls.

IN CASE OF DOUBT DO NOT HESITATE TO ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

8- INTERACTIONS WITH OTHER MEDICINES:

TO AVOID POSSIBLE INTERACTIONS BETWEEN SEVERAL MEDICATIONS, ALWAYS INFORM YOUR DOCTOR OR PHARMACIST OF ANY OTHER TREATMENT YOU ARE TAKING. The combination of Indapamide BEKER® LP is not recommended with:

Avoid taking Indapamide BEKER® LP with lithium (used to treat depression) due to the risk of increased blood lithium levels.

*Drugs used for heart rhythm disorders (e.g., quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, ibutilide, dofetilide, digoxin, bretylium).

*Drugs used to treat mental disorders: depression, anxiety, schizophrenia (such as amisulpride, sulpiride, sultopride, iloperid, haloperidol, droperidol).

*Bepidil (used to treat angina).

*Cisapride, difenhydramin (treatment of gastrointestinal disorders).

*Antibiotics (sparfloxacin, moxifloxacin, erythromycin injection).

*Vinorelbine injection (treatment of symptomatic cognitive impairment in elderly patients, including memory loss).

*Halofantrine (antiparasitic drug used to treat certain types of malaria).

*Pentamidine (used to treat certain types of pneumonia).

*Antihistamines (mizolastine, astemizole, terfenadine).

*Nonsteroidal anti-inflammatory drugs or high doses of acetylsalicylic acid.

*Angiotensin-converting enzyme (ACE) inhibitors (used to treat high blood pressure and heart failure).

*Amphotericin B injection (antifungal medication).

*Oral corticosteroids used to treat various conditions including severe asthma and rheumatoid arthritis.

*Stimulant laxatives.

*Zinc (to treat muscle stiffness) occurring in diseases such as multiple sclerosis).

*Alloaurinol (for the treatment of gout).

*Potassium-sparing diuretics (e.g., amiloride, spironolactone, triamterene).

*Metformin (to treat diabetes).

*Iodinated contrast agents (used for X-ray examinations).

*Calcium tablets or other calcium supplements.

*Cyclosporine, tacrolimus or other immunosuppressants used following an organ transplant, for the treatment of autoimmune diseases, or severe rheumatic or dermatological diseases.

*Tetracycline (to treat Crohn's disease).

*Methadone (used to treat drug addiction).

9- PREGNANCY, BREAST-FEEDING AND FERTILITY:

Pregnancy:

If you are pregnant or breastfeeding, think you may be pregnant, or are planning to become pregnant, ask your doctor or pharmacist before taking this medicine.

Pregnancy:

The use of this medicine is not recommended during pregnancy.

diuretics can cause fetal-placental ischemia, resulting in growth retardation.

Breastfeeding:

Breastfeeding is not recommended (passage into breast milk).

IN GENERAL, DURING PREGNANCY AND BREASTFEEDING, ALWAYS ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE BEFORE TAKING ANY MEDICATION.

10- DRIVERS AND MACHINE OPERATORS:

Individual reactions related to a decrease in blood pressure may occur in some patients. Consequently, the ability to drive vehicles or operate machinery may be reduced.

11- UNDESIRABLE EFFECTS:

Like all medicines, Indapamide BEKER® LP may cause side effects:

Stop taking this medicine and consult your doctor immediately if you notice any of these serious side effects.

*Angioedema and/or hives: severe skin reactions: swelling of the extremities or face, lips or tongue, mucous membranes of the throat or airways which may cause difficulty in breathing or swallowing.

*Severe skin reactions, such as intense rashes, reddening of the skin all over the body, severe itching, blisters, peeling and swelling of the skin, inflammation of the mucous membranes (Stevens-Johnson syndrome) or other allergic reactions.

*Life-threatening irregular heartbeat.

*Pancreatitis, which may lead to intense abdominal and back pain along with severe discomfort.

*Brain disease caused by liver disease (Hepatic Encephalopathy).

*Inflammation of the liver (Hepatitis).

*Muscle Weakness, cramps, muscle tenderness or pain, especially if accompanied by a general feeling of unwellness or a high fever, could indicate abnormal muscle breakdown.

The following side effects have been observed:

Common side effects:

- Allergic-like symptoms, rashes Maculopapular,
- Decreased blood potassium levels

Uncommon side effects:

- Vomiting
- Decreased blood sodium levels
- Purpura (purple hemorrhagic lesion of the skin or mucous membranes)
- Erectile dysfunction

Rare side effects:

- Decreased blood chloride and magnesium levels
- Dizziness
- Fatigue
- Headache
- Paresthesia (tingling, prickling, numbness)
- Nausea
- Constipation
- Dry mouth

Very rare side effects:

- Abnormally low or absent levels of certain white blood cells
- Aplastic anemia
- Hemolytic anemia
- Decreased white blood cell count
- Decreased platelet count
- Increased blood calcium level
- Heart rhythm disturbances, arrhythmia
- Hypotension
- Inflammation of the pancreas
- Impaired liver function
- Angioedema
- Hives
- Lyell's syndrome
- Stevens-Johnson syndrome
- Renal failure

Side effects of unknown frequency:

- Potassium depletion with abnormal decrease in blood potassium levels, particularly serious in high-risk individuals
- Abnormal decrease in blood sodium levels
- Brief and sudden loss of consciousness
- Myopia
- Blurred vision
- Visual disturbances
- Acute angle-closure glaucoma
- Choroidal effusion
- Possible occurrence of hepatic encephalopathy in cases of liver failure
- Liver inflammation
- Possible worsening of pre-existing systemic lupus erythematosus
- Photosensitivity reactions
- Muscle twitching, muscle weakness, myalgia, rhabdomyolysis
- Torsade de pointes
- QT interval prolongation Electrocardiogram
- Elevated blood glucose levels
- Elevated blood uric acid levels
- Elevated liver enzyme levels

Reporting suspected undesirable effects:

If you experience any undesirable effects, please tell your doctor or pharmacist. This applies to any side effect not mentioned in this leaflet. You can report side effects directly via the Algerian national reporting system: National Center for Pharmacovigilance and Medicovigilance (CNPM)

Website: www.cnpm.org.dz, and the Senegalese Pharmaceutical Regulatory Agency (ARP), website: www.arp.sn

REPORT TO YOUR DOCTOR OR PHARMACIST ANY UNDESIRABLE EFFECTS NOT MENTIONED IN THIS LEAFLET.

12- OVERDOSE:

If you took more Indapamide BEKER® LP than you should: consult your doctor or pharmacist immediately.

Intake of a large amount of this medicine may cause nausea, vomiting, low blood pressure, muscle cramps, dizziness, drowsiness, confusion, and changes in the amount of urine produced by the kidneys.

13- PRECAUTIONS FOR STORAGE:

If you forgot to take Indapamide BEKER® LP, do not take a double dose to make up for the forgotten dose. Continue your treatment the next day at a rate of one tablet per day.

14- PRECAUTIONS FOR STORAGE:

-Store in original packaging at temperatures not exceeding 25°C.

-Keep out of reach of children.

-Do not use after the expiration date shown on the pack.

List II

MA Holder: Laboratoires BEKER - Alloul for distal N° 2- Dar El Beida - Algiers - Algeria.

Manufacturer: Laboratoires BEKER - Area of Activities, Expansion of Dar El Beida - Palmar N°sonier distal N°18 - Algiers - Algeria.

Packaging: SOCAFI PHARMA - Plaine Technoparc n° 1793 III - Dakar - Senegal

E-mail: socafi.invest@socafipharm.com

Site web: www.socafi.sn

Date of the last update: October 2024

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