

PACKAGE LEAFLET: INFORMATION FOR THE USER

INDAPAMIDE 1.5 mg prolonged-release film-coated tablets Indapamide

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What INDAPAMIDE 1.5 mg, prolonged-release film-coated tablet is and what it is used for?
2. Before you take INDAPAMIDE 1.5 mg, prolonged-release film-coated tablet
3. How to take INDAPAMIDE 1.5 mg, prolonged-release film-coated tablet?
4. Possible side effects
5. How to store INDAPAMIDE 1.5 mg, prolonged-release film-coated tablet?
6. Further information

The name of the medicinal product is Indapamide 1.5 mg, prolonged-release film-coated tablet, but in the remainder of this leaflet it will be called INDAPAMIDE

1. WHAT INDAPAMIDE, IS AND WHAT IT IS USED FOR

This medicine is intended to reduce high blood pressure (hypertension).

It is a prolonged-release film-coated tablet containing indapamide as active ingredient. Indapamide is a diuretic. Most diuretics increase the amount of urine produced by the kidneys. However, indapamide is different from other diuretics, as it only causes a slight increase in the amount of urine produced.

2. BEFORE YOU TAKE INDAPAMIDE

Do not take INDAPAMIDE,

- if you are allergic to indapamide or any other sulphonamide or to any of the other ingredients of **INDAPAMIDE**,
- If you have severe kidney disease,
- If you have severe liver disease, or suffer from a condition called hepatic encephalopathy,
- If you have low potassium levels in your blood.

Take special care with INDAPAMIDE ,:

- if you have liver problems,
- if you have diabetes,
- if you suffer from gout,
- if you have any heart rhythm problems or problems with your kidneys,
- if you need to have a test to check how well your parathyroid gland is working.

You should tell your doctor if you had sensitivity to sunlight.

Your doctor may give you blood tests to check for low sodium or potassium levels or high calcium levels.

If you think any of these situations may apply to you or you have any questions or doubts about taking your medicine, you should consult your doctor or pharmacist.

Athletes should be aware that this medicine contains an active ingredient, which may give a positive reaction in doping tests.

Taking other medicines.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

You should not take Indapamide 1.5 mg with lithium (used to treat depression) due to the risk of increased levels of lithium in the blood.

Make sure to tell your doctor if you are taking any of the following medicines, as special care may be required:

- medicines used for heart rhythm problems (e.g. quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, ibutilide, dofetilide, digitalis),
- medicines used to treat mental disorders such as depression, anxiety, schizophrenia... (e.g. tricyclic antidepressants, antipsychotic drugs),
- bepridil (used to treat angina pectoris, a condition causing chest pain),
- cisapride, diphermanil (used to treat gastro-intestinal problems),
- sparfloxacin, moxifloxacin (antibiotics used to treat infections),
- halofantrine (antiparasitic drug used to treat certain types of malaria),
- pentamidine (used to treat certain types of pneumonia),
- mizolastine (used to treat allergic reactions, such as hay fever),
- non-steroidal anti-inflammatory drugs for pain relief (e.g. ibuprofen) or high doses of acetylsalicylic acid,
- angiotensin converting enzyme (ACE) inhibitors (used to treat high blood pressure and heart failure),
- oral corticosteroids used to treat various conditions including severe asthma and rheumatoid arthritis,
- stimulant laxatives,
- baclofen (to treat muscle stiffness occurring in diseases such as multiple sclerosis),
- potassium-sparing diuretics (amiloride, spironolactone, triamterene),
- metformin (to treat diabetes),
- iodinated contrast media (used for tests involving X-rays),
- calcium tablets or other calcium supplements,
- ciclosporin, tacrolimus or other medicines to depress the immune system after organ transplantation, to treat autoimmune diseases, or severe rheumatic or dermatological diseases,
- tetracosactide (to treat Crohn's disease).

Pregnancy and breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

This medicine is not recommended during pregnancy. When a pregnancy is planned or confirmed, the switch to an alternative treatment should be initiated as soon as possible. Please tell your doctor if you are pregnant or wish to become pregnant.

The active ingredient is excreted in milk. Breastfeeding is not advisable if you are taking this medicine.

Driving and using machines:

This medicine 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.

Important information about some of ingredients of INDAPAMIDE :

This medicine 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 medicinal product.

3 HOW TO TAKE INDAPAMIDE ?

Instructions for proper use:

One tablet each day, preferably in the morning. The tablets can be taken irrespective of meals. They should be swallowed whole with water. Do not crush or chew them.

Treatment for high blood pressure is usually life-long.

If you take more INDAPAMIDE , than you should:

If you have taken too many tablets, contact your doctor or pharmacist immediately.

A very large dose of Indapamide 1.5 mg could cause nausea, vomiting, low blood pressure, cramps, dizziness, drowsiness, confusion and changes in the amount of urine produced by the kidneys.

If you forget to take INDAPAMIDE

If you forget to take a dose of your medicine, take the next dose at the usual time.

Do not take a double dose to make up for a forgotten dose.

If you stop taking INDAPAMIDE

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

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Indapamide 1.5 mg, prolonged-release film-coated tablet can cause side effects, although not everybody gets them.

These can include:

- *Commonly (less than 1 patient per 10 but more than 1 per 100):* low potassium in the blood, which may cause muscle weakness.
- *Uncommonly (less than 1 patient per 100 but more than 1 per 1000):* vomiting, allergic reactions, mainly dermatological, such as skin rashes, purpura (red pinpoint spots on skin) in subjects with a predisposition to allergic and asthmatic reactions.
- *Rarely (less than 1 patient per 1000 but more than 1 per 10,000):*
 - Feeling of tiredness, dizziness, headache, pins and needles (paresthesia);
 - Gastro-intestinal disorders (such as nausea, constipation), dry mouth;
 - Increased risk of dehydration in the elderly and in patients suffering from heart failure.
- *Very rarely (less than 1 patient per 10,000):*
 - Heart rhythm irregularities, low blood pressure;
 - Kidney disease;
 - Pancreatitis (inflammation of the pancreas which causes upper abdominal pain), abnormal liver function. In cases of liver failure, there is a possibility of getting hepatic encephalopathy;
 - 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) and anaemia (decrease in red blood cells);

- Angioedema and/or urticaria, severe skin manifestations. Angioedema is characterised by swelling of the skin of extremities or face, swelling of the lips or tongue, swelling of the mucous membranes of the throat or airways resulting in shortness of breath or difficulty of swallowing. If this occurs, contact your doctor immediately.

If you suffer from systemic lupus erythematosus (a type of collagen disease), this might get worse. Cases of photosensitivity reactions (change in skin appearance) after exposure to the sun or artificial UVA have also been reported.

Some changes may occur in your laboratory parameters and your doctor may need to give you blood tests to check your condition. The following changes in laboratory parameters may occur:

- . low potassium in the blood,
- . low sodium in the blood that may lead to dehydration and low blood pressure,
- . increase in uric acid, a substance which may cause or worsen gout (painful joint(s) especially in the feet),
- . increase in blood glucose levels in diabetic patients,
- . increase of calcium in blood.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

5. HOW TO STORE INDAPAMIDE ?

Keep out of the reach and sight of children.

Do not use **INDAPAMIDE** after the expiry date which is stated on the carton.

<Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.>

6. FURTHER INFORMATION

What **INDAPAMIDE** contains

- The active substance is Indapamide
- The other ingredients are:

Lactose monohydrate, hypromellose, povidone, anhydrous colloidal silica, magnesium stearate, titanium dioxide (E171), macrogol 6000, pregelatinized starch.

What **INDAPAMIDE** looks like and contents of the pack

White, prolonged-release film-coated tablets. **INDAPAMIDE 1.5 mg, prolonged-release film-coated tablet** is available in 30, 90 or 100 tablets.

Marketing Authorisation Holder is:

{Name and address}

<{tel}>

<{fax}>

<{e-mail}>

The manufacturer is:

McDermott Laboratories (T/A Gerard Laboratories),35-36 Industrial Estate, Grang Road, Dublin 13, Ireland.

Merck Farma y Quimica, Poligono Merck, 08100 Mollet del Valles, BARCELONA, SPAIN

Merck Génériques, 34 rue Saint Romain 69359 Lyon cedex 08, France

Merck Génériques, ZAC des Gaulnes, 10 Boulevard de Lattre de Tassigny, 69330 Meyzieu, France

This leaflet was last approved in {MM/YYYY}.

<Detailed information on this medicine is available on the web site of {Name of MS/Agency}.