

PACKAGE LEAFLET: INFORMATION FOR THE USER

INDAP

2.5MG CAPSULES

INDAPAMIDE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• 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 only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What indapamide is and what it is used for
2. Before you take indapamide
3. How to take indapamide
4. Possible side effects
5. How to store indapamide

1. WHAT INDAPAMIDE IS AND WHAT IT IS USED FOR

The name of your medicine is Indap 2.5mg Capsules (called Indapamide throughout this leaflet). It belongs to a group of medicines called diuretics (water Capsules).

Indapamide can be used for treating:

- High blood pressure (hypertension). It may be used on its own or in combination with other medicine for high blood pressure.

2. BEFORE YOU TAKE INDAPAMIDE

Do not take indapamide if:

- You are allergic (hypersensitive) to indapamide or any of the other ingredients of this medicine. Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, throat, or tongue.
- You are allergic (hypersensitive) to sulphonamide drugs (such as Co-trimoxazole)
- You have recently had a stroke
- You have severe kidney disease
- You have ever had severe liver problems or suffer from a condition called hepatic encephalopathy

(liver problems which affect your brain and central nervous system)

- You have low levels of potassium in your blood (hypokalaemia)

Do not take the medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking indapamide.

Take special care with indapamide and check with your doctor or pharmacist before taking this medicine if:

- In the past you have had low levels potassium in your blood. Low levels of potassium can occur in someone with heart disease or high blood pressure.
- You suffer from gout or have diabetes
- You have kidney problems
- You have an overactive thyroid gland (hyperparathyroidism)
- You have heart rhythm problems
- You have liver problems

You should tell your doctor if you have had photosensitivity reactions.

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

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. This includes medicines you buy without a prescription, including herbal medicines. This is because indapamide can affect the way some medicines work. Also some medicines can affect the way indapamide works.

In particular, tell your doctor if you are taking any of the following:

- Lithium (used to treat depression). You should not take indapamide with lithium due to the risk of increased levels of lithium in the blood
- Medicines for heart rhythm problems such as quinidine, hydroquinidine, disopyramide, amiodarone, sotalol, ibutilide, dofetilide or digitalis
- Bepiridil (used to treat angina pectoris, a condition causing chest pain)
- Other water Capsules (such as furosemide). Your doctor may want to monitor you more closely.
- Steroids such as prednisolone or hydrocortisone
- Stimulant laxatives
- Medicines used to treat mental disorders such as depression, anxiety or schizophrenia (for example tricyclic antidepressants, antipsychotic drugs, neuroleptics)
- Moxifloxacin (antibiotic used to treat infection)
- Pentamidine (used to treat certain types of pneumonia)
- Halofantrine (antiparasitic drug used to treat certain types of malaria)
- 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 (aspirin)
- 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
- 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 Capsules 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)
- Cisapride (used to treat reduced movement of the gullet and stomach)
- Diphemanil (used to treat gastro-intestinal problems such as ulcers, too much acid, overactive digestive system)

Driving and using machines:

Indapamide may make you feel tired or dizzy (see section 4). If this happens do not drive or use any tools or machines. These side effects are more likely to occur, at the start of the treatment and after dose increases.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking indapamide.

Pregnancy and breast-feeding

Indapamide is not recommended during pregnancy.

- Talk to your doctor before taking this medicine if you are pregnant, might become pregnant, or think you may be pregnant.
- Do not use this medicine if you are breast-feeding or planning to breast-feed.

Indapamide contains lactose.

If you have been told by your doctor that you cannot digest or tolerate some sugars, talk to your doctor before taking this medicine.

3. HOW TO TAKE INDAPAMIDE

Always take indapamide exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Keep taking this medicine until your doctor tells you to stop. It may take several months before this medicine shows its full effect.
- Capsules can be taken with or without food
- Swallow the Capsules whole with a drink of water

Adults and Elderly

The usual dose is one Capsule, once a day, taken in the morning

If you take more indapamide than you should

If you take more Capsules than you should, tell your doctor or go to your nearest hospital casualty department immediately.

Take the carton and any indapamide Capsules left with you so that the doctors know what you have taken.

Taking too much indapamide may make you feel or be sick (nausea or vomiting), cause low blood pressure, cramps, dizziness, drowsiness, confusion and changes in the amount of urine produced by the kidneys due to severe dehydration.

If you forget to take indapamide

Do not take a double dose to make up for a forgotten Capsule. Miss it out and take the next dose at the usual time.

If you stop taking indapamide

Keep taking indapamide until your doctor tells you to stop taking it. Treatment for high blood pressure is usually life-long.

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 can cause side effects, although not everybody gets them.

Stop taking indapamide and see your doctor or go to a hospital straight away if:

- You get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria). This may mean you are having an allergic reaction to indapamide Capsules
- You get symptoms including blistering or peeling of your skin, flu-like symptoms and a high temperature. This could be a rare but serious condition called epidermal necrolysis.
- You get an irregular heartbeat (Torsade de pointes), which could be life-threatening.

Tell your doctor as soon as possible if you have any of the following side-effects:

- You feel tired, weak, confused and have muscles that ache, are stiff or do not work well. This may be due to low sodium levels in your blood (hyponatraemia)
- You feel irritable and your muscles twitch. This may be due to an imbalance in your blood called metabolic alkalosis
- Itchy, lumpy rash. You may also have a high temperature, sore throat, headache or diarrhoea
- You get more infections than usual or bruise more easily. This could be caused by problems with your blood.
- You get increased thirst, hunger and weight loss. These could be signs of diabetes

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days. Also tell them if you notice any side effects not listed in this leaflet.

Common (may affect up to 1 in 10 people):

- low potassium in the blood, which may cause muscle weakness;
- allergic reactions, mainly dermatological, such as skin rashes in patients with a predisposition to allergic and asthmatic reactions.

Uncommon (may affect less than 1 in 100 people):

- being sick (vomiting);
- purpura (red pinpoint spots on skin).

Rare (may affect less than 1 in 1000 people):

- feeling of tiredness, dizziness, headache, pins and needles (paresthesia);
- nausea (feeling sick), constipation, dry mouth;
- increased risk of dehydration in the elderly and in patients suffering from heart failure.

Very rare (may affect less than 1 in 10,000 people):

- heart rhythm irregularities (causing palpitations, feeling of the heart pounding), low blood pressure;
- kidney disease (causing symptoms of tiredness, increased need to urinate, itchy skin, feeling sick, swollen extremities);
- pancreatitis (inflammation of the pancreas which causes upper abdominal pain);
- abnormal liver function (with symptoms such as tiredness, loss of appetite, feeling or being sick, swollen extremities, yellow skin);
- 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 around the eyes, lips, hands or feet. It may cause swelling of the throat, tongue or airways resulting in shortness of breath or difficulty of swallowing. If this occurs, contact your doctor immediately.
- increase in calcium in the blood

Frequency not known (cannot be estimated from available data):

- in cases of liver failure, there is a possibility of getting hepatic encephalopathy (liver problems which affect the brain and central nervous system)
 - dizziness, lightheadedness, fainting when you stand or sit up quickly (due to low blood pressure)
- loss of appetite (anorexia), indigestion
- abnormal ECG heart trace
 - hepatitis
 - The following changes in your blood test results may occur:
 - Increase in uric acid, a substance which may cause or worsen gout (painful joints especially in the feet)
 - Increased levels of liver enzymes

If you suffer from systemic lupus erythematosus (a disorder of the immune system leading to inflammation and damage to the joints, tendons and organs with symptoms including skin rashes, tiredness, loss of appetite, weight gain and joint pain), 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 blood and your doctor may need to give you blood tests to check your condition. The following changes in your blood test results 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.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

By reporting side effects you can help provide more information on the safety of this medicine.

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. The expiry date refers to the last day of that month.
- Do not use indapamide if you notice that the Capsules are crumbling, broken or discoloured.
- Indapamide Capsules do not need any special storage conditions.

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.

This leaflet was last revised in February 2015