

Indapamide Sandoz®

Indapamide hemihydrate tablets

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Indapamide Sandoz.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risk of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist. Keep this leaflet with the medicine.

WHAT INDAPAMIDE SANDOZ IS USED FOR

You have been prescribed Indapamide Sandoz for high blood pressure.

Indapamide Sandoz contains the active ingredient indapamide hemihydrate which belongs to a group of medicines called chlorosulphamoyl diuretics (a type of "fluid" or "water").

Indapamide Sandoz is available only with a doctor's prescription.

There is no evidence that Indapamide Sandoz is addictive.

Why Indapamide Sandoz is used for high blood pressure

Everyone has blood pressure. This pressure helps to circulate blood all around the body. Your blood pressure may be different at different times of the day, depending on how busy or stressed you are.

You have high blood pressure (also known as hypertension) which is when your blood pressure stays higher than is needed, even when you are calm and relaxed.

If high blood pressure is not treated it can lead to serious health problems. You may feel fine and have no symptoms, but eventually it can cause stroke, heart disease and kidney failure.

Indapamide Sandoz helps to lower your blood pressure.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

BEFORE YOU TAKE INDAPAMIDE SANDOZ

There are some people who should not take Indapamide Sandoz. Please read the lists below. If you think any of these situations apply to you, or you have any questions, please consult your doctor or pharmacist.

When you must not take it

Do not take Indapamide Sandoz if:

- You are allergic to indapamide, or any of the other ingredients of Indapamide Sandoz listed at the end of this leaflet.
- You are allergic to sulphonamide (sulpha) antibiotics, or to thiazide diuretics (a type of "fluid" or "water" tablet).
- You are pregnant or trying to become pregnant.
- You are breastfeeding or plan to breastfeed.
- You have severe kidney disease.

- You have severe liver disease or suffer from a condition called hepatic encephalopathy (liver problems which affect the brain and central nervous system).
- You have low potassium levels in your blood.
- The packaging is torn or shows signs of tampering, or the tablets do not look quite right.

Before you start to take it

Tell your doctor straight away if:

- You have an intolerance to lactose.
- You have or have had any other health problems, including:
 - High or low levels of potassium, sodium, or other problems with salt balance.
 - Gout.
 - Diabetes.
 - Increased sensitivity to sunlight (photosensitivity reactions).
 - Systemic lupus erythematosus (a disease affecting the skin, joints and kidneys).
 - Heart rhythm problems.
 - Problems with your kidneys.
 - A test to check how well your parathyroid gland is working.
- Athletes should be aware that this medicine contains an active ingredient, which may give a positive reaction in doping tests.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Taking Indapamide Sandoz may change the effect of some medicines, and some medicines may affect how well Indapamide Sandoz works. You may need different amounts of your medication or to take different medicines.

You should not take Indapamide Sandoz with lithium medications (used to treat mood swings and some types of depression) due to the risk of increased levels of lithium in the blood.

The medicines that may interact with Indapamide Sandoz include the following:

- Some steroid medicines.
- Diuretics (sometimes called "fluid" or "water" tablets).
- Some medications used to treat high blood pressure, a fast or irregular heartbeat and other heart conditions.
- Medicines to treat mental illnesses such as some medicines for epilepsy, anxiety, schizophrenia and some other antidepressants.
- Non-steroidal anti-inflammatory drugs for pain relief (e.g. ibuprofen) or high doses of aspirin.
- Calcium supplements.
- Stimulant laxatives.
- Baclofen (a medicine used to treat muscle stiffness occurring in diseases such as multiple sclerosis).
- Metformin (a medicine used to treat diabetes).
- Cyclosporin, tacrolimus (medicines used to treat certain problems with the immune system).

- Amphotericin B by IV, erythromycin by IV (antibiotic medicines used to treat infections).
- Medicines used during scans to see the images of your body.
- Diphemanil (used to treat excessive sweating).
- Moxifloxacin (an antibiotic medicine used to treat infections).
- Pentamidine (a medicine used to treat certain types of pneumonia).
- Allopurinol (a medicine used to treat gout)

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

For older people or children

- Elderly people can generally use Indapamide Sandoz safely. However, some older people have reduced kidney function - in which case additional care may be required.
- **Indapamide Sandoz is not recommended for use in children**

HOW TO TAKE INDAPAMIDE SANDOZ

Follow all directions given to you by your doctor or pharmacist carefully. If you do not understand the instructions, ask your doctor or pharmacist for help.

Your doctor will select a dose when they prescribe Indapamide Sandoz for you. The usual dose is one tablet once daily.

Swallow your tablet with water, preferably in the morning. Do not crush or break them.

How long to take Indapamide Sandoz

Indapamide Sandoz can help to control your blood pressure, but cannot cure it. Indapamide Sandoz treatment is usually for life - so you should keep taking the tablets regularly unless advised otherwise by your doctor.

If you forget to take it

If your next usual dose is less than 6 hours away, just leave out the dose that you missed. Take the next dose at the usual time and continue as normal.

If your next dose is more than 6 hours away, take the dose you have missed as soon as you realise. Then take the next dose at the usual time and continue as normal.

Do not try to make up for missed doses by taking more than one dose at a time.

If you take too much (overdose)

Taking too much Indapamide Sandoz (an overdose) may cause low blood pressure (also known as hypotension). Other effects like sickness, cramps, sleepiness, confusion, kidney problems, salt and water disturbances are possible. You may require urgent medical attention.

If you think that you or anyone else may have taken too much Indapamide Sandoz then act immediately

- Telephone your doctor or the Poisons Information Centre (13 11 26 in Australia), or go to the Accident and Emergency department at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

WHILE YOU ARE TAKING INDAPAMIDE SANDOZ

Things you must do

Take Indapamide Sandoz exactly as your doctor has prescribed. Otherwise you may not get the benefits from treatment.

Tell all doctors, dentists and pharmacists who are involved with your treatment that you are taking Indapamide Sandoz.

Make sure you drink enough water during exercise and hot weather especially if you sweat a lot. This will help you avoid any dizziness or light-headedness caused by a sudden drop in blood pressure.

Tell your doctor straight away if you have excessive vomiting or diarrhoea while taking Indapamide Sandoz as these may affect how Indapamide Sandoz is processed by your body. If you experience any of the following symptoms, you may be dehydrated because you are losing too much water:

- dry mouth or thirst
- fainting
- weakness
- tiredness or drowsiness
- muscle pain or cramps
- fast heart beat

Things you must not do

Do not take Indapamide Sandoz to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how Indapamide Sandoz affects you.

You may feel light-headed or dizzy when you begin to take Indapamide Sandoz. This is because your blood pressure is falling. Symptoms are likely to be made worse if you drink alcohol or take strong pain killers.

If you have these symptoms when standing up or getting out of bed then getting up more slowly can help. This allows your body to get used to the change in position and blood pressure.

Indapamide Sandoz may cause your skin to become more sensitive to the sun. If this happens you should stop taking Indapamide Sandoz and contact your doctor.

If you have these symptoms and they don't get better in a short time then talk to your doctor.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Indapamide Sandoz.

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

Indapamide Sandoz helps most people with high blood pressure, but it may sometimes have unwanted side effects. These can include:

- Headache.
- Feeling tired or as if you have less energy, difficulty sleeping.
- Feeling faint, light-headed, or dizzy.
- Feeling nervous or anxious.
- Feeling sick or having an upset stomach, having an uncomfortable feeling after eating,

vomiting, constipation, diarrhoea or loss of appetite.

- Muscle pain, back pain, joint pain, cramp or tingling or numbness of the hands or feet.
- Skin rashes or other allergic reactions.
- Gout.
- Increased sensitivity to sunlight.
- An increased risk of becoming dehydrated (in elderly patients and in patients with heart failure).
- Low potassium levels. Symptoms of low potassium can include a number of those listed above, and very occasionally this may be severe.
- Kidney disease.
- Inflammation of the pancreas.
- Hepatic encephalopathy (liver problems which affect the brain and central nervous system).
- Abnormal liver function.
- If you suffer from systemic lupus erythematosus (a type of collagen disease), this might get worse.
- Changes in blood cells, such as thrombocytopenia (a decrease in the number of platelets which causes easy bruising and nasal bleeding), leucopenia (a decrease of white blood cells which may cause unexplained fever, soreness of the throat or other flu-like symptoms) and anaemia (a decrease in red blood cells).
- Low blood pressure, unusual heart beat.
- Blurred or changed vision.
- Dry mouth.
- Cystitis

Most of these side effects are mild when they occur. Do not be alarmed by the following lists of side effects. You may not experience any of them. However, if you do - or if you notice anything else that is making you feel unwell - you should consult your doctor or pharmacist.

If any of the signs below occur then tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital:

- Swelling of your lips, face, mouth, tongue or throat.
- Purple spots with occasional blisters on the front of your arms and legs and/or around your neck and ears (A rare condition known as Stevens-Johnson Syndrome).
- Toxic epidermal necrolysis.
- A fast and irregular heart beat.
- Severe blisters, skin rash, itching or other allergic reactions.

These side effects are extremely rare but can become serious.

AFTER TAKING INDAPAMIDE SANDOZ

Storage

Keep your tablets in the pack until it is time to take them. Keep them in a cool, dry place where it stays below 25°C. Keep them where children cannot reach them.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

PRODUCT DESCRIPTION

What it looks like

Indapamide Sandoz 2.5mg - white, round, biconvex, sugar-coated tablets.

Available in blisters of 90 tablets.

Ingredients

Active ingredient:

- Indapamide Sandoz 2.5mg - 2.5mg of indapamide hemihydrate.

Inactive ingredients:

- lactose monohydrate
- povidone
- starch
- maize
- magnesium stearate
- Opaseal clear P-2-0300G (ethyl acetate, stearic acid, polyvinyl acetate phthalate, purified water, industrial methylated spirit 74 OP)
- purified talc
- calcium carbonate
- acacia
- titanium dioxide
- sucrose
- Opaglos 6000P off-white (shellac, industrial methylated spirit 74 OP, beeswax white, carnuba wax).

This medicine does not contain gluten, tartrazine or any other azo food dyes.

Supplier

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2.5mg film-coated tablet: AUST R 169291 (blister)