

APO-Indapamide SR Tablets

Indapamide hemihydrate

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about indapamide slow-release (SR) tablets. 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 risks of you using 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.

You may want to read it again.

What this medicine is used for

Indapamide SR is used to treat mild to moderate high blood pressure (also known as hypertension). These tablets release the active ingredient, indapamide, progressively over 24 hours.

Indapamide belongs to a group of medicines called diuretics (a type of 'fluid' or 'water' tablet).

Indapamide is thought to lower blood pressure by relaxing some of the blood vessels in the body. The blood vessels can then carry the same volume of blood more easily.

Everyone has blood pressure. This pressure helps to move your 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 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.

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

Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

This medicine is not addictive.

There is not enough information to recommend the use of this medicine in children.

Before you take this medicine

There are some people who should not take indapamide SR. 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 this medicine if:

- You are allergic to indapamide, or any of the other ingredients of indapamide SR listed at the end of this leaflet.
- You are allergic to sulfonamide (sulfa) 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 breast-feed.
- 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.
- The expiry date (EXP) on the pack has passed.

Before you start to take it

Tell your doctor straight away if:

- You have an intolerance to lactose.
- You have or have had any 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.
 - If you experience a decrease in vision or eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye or an increase of pressure in your eye and can happen within hours to a week of taking indapamide SR. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulfonamide allergy, you can be at higher risk of developing this.
 - You have muscle disorders including muscle pain, tenderness, weakness or cramps.
 - 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 a pharmacy, supermarket or health food shop.

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

You should not take indapamide SR 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 SR include the following:

- Some steroid medicines.
- Diuretics (sometimes called "fluid" or "water" tablets, e.g. amiloride, spironolactone, triamterene).
- Medicines used for heart rhythm problems (e.g. disopyramide, amiodarone, sotalol, flecainide).

- Some medications used to treat high blood pressure (e.g. angiotensin converting enzyme (ACE) inhibitors), 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 (e.g. tricyclic antidepressants, antipsychotic drugs, neuroleptics such as: droperidol, haloperidol, chlorpromazine, trifluoperazine, amisulpride, sulpiride, psychoanaleptics).
- Antiparasitic medicines used to treat certain types of malaria (e.g. chloroquine).
- Pentamidine (a medicine used to treat certain types of pneumonia).
- Antihistamines used to treat allergic reactions, such as hay fever.
- Medicines used to treat nausea and vomiting (e.g. ondansetron, domperidone).
- Medicines used to treat cancer (e.g. vandetanib, oxaliplatin).
- Anagrelide (used to reduce elevated blood platelet counts).
- 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).
- Medicines used to treat fungal infections (e.g. Amphotericin B (amphotericin) by IV, fluconazole).
- Medicines used during scans to see the images of your body.
- Medicines used to treat gastro-intestinal problems (e.g. cisapride, papaverine).
- Medicines used to treat bacterial infections (e.g. Moxifloxacin, ciprofloxacin, clarithromycin, erythromycin by IV).
- Allopurinol (a medicine used to treat gout).
- Tetracosactide (tetracosactrin) (to treat Crohn's disease).
- Methadone (used to treat addiction).
- Cilostazol (used to treat cramp-like pain in the legs when you walk).

Your doctor or pharmacist has 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 SR safely. However, some older people have reduced kidney function - in which case additional care may be required.
- **Indapamide SR is not recommended for use in children.**

How to take this medicine

Follow all directions given to you by your doctor carefully.

They may differ to the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how much of this medicine you should take.

This will depend on your condition and whether you are taking any other medicines.

The usual dose is one tablet once daily.

How to take it

Swallow your tablet whole with a glass of water, preferably in the morning.

Do not crush or break the tablets.

Take this medicine at about the same time each day.

Taking it at the same time each day will have the best effect and will also help you remember when to take it.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose (within 6 hours), skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for missed doses.

This may increase the chance of unwanted side effects.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Taking too much indapamide SR (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.

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking this medicine

Things you must do

Take indapamide SR exactly as your doctor has prescribed. Otherwise, you may not get the benefits from treatment.

Tell all doctors, dentists and pharmacists who treat you that you are taking this medicine.

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 this medicine as these may affect how this

medicine 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 or weakness.
- Tiredness or drowsiness.
- Muscle pain or cramps.
- Fast heartbeat.
- Passing less urine than normal.

Things you must not do

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

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

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

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

You may feel light-headed or dizzy when you begin to take indapamide SR 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.

This medicine may cause your skin to become more sensitive to the sun.

If this happens you should stop taking indapamide SR and contact your doctor.

If you have these symptoms and they do not 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 this medicine.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. Indapamide SR helps most people with high blood pressure, but it may have unwanted side effects, these include:

Do not be alarmed by the following lists of side effects. You may not experience any of them.

- 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 or constipation.
- Muscle weakness, pain, tenderness, cramp, tingling or numbness of the hands or feet (and particularly if at the same time you feel unwell or have a high temperature, it may be caused by an abnormal muscle breakdown (not known)).
- 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 blood levels of potassium, magnesium or chlorine.
- 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 heartbeat.
- High level of calcium in blood
- Blurred or changed vision, short sightedness (myopia).
- Decrease in vision or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye or acute angle-closure glaucoma).
- Dry mouth.
- Cystitis.
- Erectile dysfunction.

Most of these side effects are mild when they occur. Do not be alarmed by this list of possible 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.

Changes may occur in your laboratory parameters (blood tests) and your doctor may need to give you blood tests to check your condition. The following changes in laboratory tests 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), increase in blood glucose levels in diabetic patients, increased levels of liver enzymes.

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 heartbeat.
- Severe blisters, skin rash, itching or other allergic reactions.

These side effects are extremely rare but can become serious.

Storage

Keep the tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store your medicine or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

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

White to off-white, round, biconvex, film coated tablets.

Blister packs of 90 tablets.

AUST R 208007.

Ingredients

Each tablet contains 1.5 mg of indapamide hemihydrate as the active ingredient.

It also contains the following:

- lactose monohydrate
- povidone
- hypromellose
- colloidal anhydrous silica
- magnesium stearate

White film coating on the tablet contains:

- polyvinyl alcohol
- macrogol 3350
- titanium dioxide
- purified talc

This medicine does not contain gluten. This medicine contains sugars as lactose.

Sponsor

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