

APO-Indapamide SR Tablets

Contains the active ingredient indapamide hemihydrate 1.5 mg

Consumer Medicine Information

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

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about Indapamide SR. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up-to-date leaflet from www.apotex.com.au.

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.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Indapamide SR Tablets. The medicine releases the active ingredient indapamide progressively over 24 hours (modified release or sustained release tablet). Indapamide belongs to a group of medicines called chlorosulphamoyl diuretics (a type of "fluid" or "water" tablet).

You have been prescribed Indapamide sustained release tablets for high blood pressure.

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

There is no evidence that this medicine is addictive.

Why this medicine 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) 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 modified (sustained) release tablets help to lower your blood pressure.

Ask your doctor if you have any questions about why Indapamide SR has been prescribed for you.

Before you take this medicine

There are some people who should not take Indapamide SR. Please read the list 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 hypersensitive to, or have had an allergic reaction to, Indapamide SR or any of the ingredients 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).** Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms. **If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.**
- **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 expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
 - an intolerance to lactose
2. You have or have had any medical conditions, especially the following:
 - High or low levels of potassium, sodium, or other problems with salt balance
 - Gout
 - Diabetes
 - Previously experienced an 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 if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may interact with Indapamide SR. These include:

- Lithium medications (used to treat mood swings and some types of depression) due to the risk of increased levels of lithium in the blood.
- 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 (e.g. imipramine).
- 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).
- Cyclosporine, 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 to treat gout)

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with Indapamide SR.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Indapamide SR.

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 carefully all directions given to you by your doctor. Their instructions may be different to the information 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.

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

How to take it

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

Do not crush or break the tablets.

Take this medicine at 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

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

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

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 take a double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

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

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.

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia or 0800 764 766 in New Zealand) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

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 are involved with your treatment that you are taking Indapamide SR.

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 SR as these may affect how Indapamide SR 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
- Passing less urine than normal

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- 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. 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 SR 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 don't get better in a short time then talk to your doctor.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking Indapamide SR or if you have any questions or concerns.

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

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

Tell your doctor if you notice any of the following:

- Headache.
- Feeling tired or as if you have less energy.
- Feeling faint, light-headed, or dizzy.
- Feeling sick or having an upset stomach.
- Muscle pain or cramp.
- Skin rashes or other allergic reactions.
- 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 diseases.
- 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.

Most of these side effects are mild when they occur.

However, if you do - or if you notice anything else that is making you feel unwell - you should consult your doctor or pharmacist.

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and you may need urgent medical attention or hospitalisation:

- 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.
- Vision problems such as visual impairment, blurred vision or short-sightedness

These side effects are extremely rare but can become serious.

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to Indapamide SR, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay 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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

APO-Indapamide SR (sustained release) tablets look like

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

Blister packs of 90 tablets.

Ingredients

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

It also contains the following inactive ingredients:

- Lactose monohydrate
- Povidone
- Hypromellose
- Colloidal anhydrous silica
- Magnesium stearate

The film coating on the tablet contains:

- Opadry II 85F18378 White (polyvinyl alcohol, macrogol, titanium dioxide and talc)

This medicine is gluten-free.

Australian Registration Numbers

- APO-Indapamide SR 1.5mg Tablets (Blister Pack)
- AUST R 208007

Sponsor

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