

# 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

**When you must not take it**

**Do not take this medicine if you have an allergy to:**

- indapamide
- sulphonamide ('sulfa') antibiotics

- thiazide diuretics
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- 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

**Do not take this medicine if you have or have had the following medical conditions:**

- severe kidney disease
- severe liver disease, hepatic coma or a condition called hepatic encephalopathy (liver problems which affect the brain and central nervous system)
- low potassium levels in your blood
- very low production of urine

**Do not take this medicine if you are taking medicines that could increase the risk of Torsades de pointes, such as:**

- antipsychotics (e.g. chlorpromazine, haloperidol, pimozide, thioridazine, trifluoperazine, amisulpride or droperidol)
- medicines to treat infections (e.g. erythromycin IV, pentamidine or moxifloxacin)
- diphemanil
- methadone

**Do not take this medicine if you are pregnant or plan to become pregnant.**

It may affect your developing baby if you take it during pregnancy.

**Do not take this medicine if you are currently breastfeeding.**

Indapamide can pass into breast milk and there is a possibility your baby may be affected.

**Do not take this medicine after the expiry date printed on the pack or the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

### ***Before you start to take it***

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have or have had any of the following medical conditions:**

- low levels of potassium, sodium or chlorine, or high levels of uric acid. If you have a salt imbalance you may feel thirsty, weak, faint, drowsy, restless, sick, or have weak or cramped muscles, or have changes in your heart rate or rhythm. You may also have gout due to high uric acid levels.
- gout
- diabetes
- an increased sensitivity to sunlight (photosensitivity reactions)
- systemic lupus erythematosus (a disease affecting the skin, joints and kidneys)
- heart rhythm problems
- liver or kidney problems
- lactose intolerance

**Your doctor may want to do a test before you start taking indapamide 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.**

**Elderly people can generally use indapamide SR safely. However, some older people have reduced kidney function - in which case additional care may be required.**

**If you have not told your doctor about any of the above, tell them before you start taking this medicine.**

### ***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.**

Some medicines must not be taken with indapamide because they may increase the risk of Torsades de pointes. These include:

- antipsychotics (e.g. chlorpromazine, thioridazine, trifluoperazine, amisulpride, droperidol, haloperidol or pimozide)
- medicines to treat infections (e.g. erythromycin IV, amphotericin B IV, pentamidine or moxifloxacin)
- antiarrhythmic medicines (e.g. disopyramide, amiodarone and sotalol)
- diphemanil, used for excessive sweating
- methadone, used to treat strong pain

Some medicines and indapamide SR may interfere with each other. These include:

- lithium, used to treat mood disorders
- sedating drugs (e.g. barbiturates, alcohol or strong pain killers)
- diuretics, used to treat excess fluid in the body
- medicines used to treat high blood pressure (e.g. ACE inhibitors or sartans)

- medicines used to treat heart problems (e.g. digoxin or quinidine)
- some medicines used to treat epilepsy or fits
- corticosteroids and non-steroidal anti-inflammatory medicines (including high-dose aspirin)
- calcium supplements or medicines containing calcium
- stimulant laxatives
- baclofen, a muscle relaxant
- metformin, used to treat diabetes
- cyclosporin and tacrolimus, used to treat certain immune system problems
- medicines containing iodine, used to diagnose some medical conditions
- allopurinol, used to treat gout
- medicines that affect CYP2C9 and CYP3A4 liver enzymes (e.g. ritonavir, ketoconazole, phenytoin or carbamazepine)
- a combination of diuretic tablets, blood pressure medicines, and non-steroidal anti-inflammatory drugs (may cause serious kidney problems)

These medicines may be affected by indapamide SR or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

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

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## **How to take this medicine**

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**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)***

**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.**

Symptoms of an overdose may include low blood pressure (also known as hypotension), sickness, cramps, sleepiness, confusion, kidney problems, salt and water disturbances.

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## **While you are taking this medicine**

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### ***Things you must do***

**If you are about to be started on any new medicines, remind your doctor and pharmacist that you are taking this medicine.**

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

**If you become pregnant or start to breastfeed while taking this medicine, tell your doctor immediately.**

**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 heart beat
- passing less urine than normal

**Keep all of your doctor's appointments so that your progress can be checked.**

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. This is especially important for patients who are at high risk of developing electrolyte (salt) disturbances, such as the elderly, patients who are taking many medicines or patients who are malnourished.

### ***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.

**If you have dizziness 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. Talk to your doctor if you have these symptoms and they do not get better in a short time.

### **Be careful when drinking alcohol while you are taking this medicine.**

If you drink alcohol or take strong pain killers, barbiturates or other medicines for blood pressure, dizziness or light-headedness may be worse.

### **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.

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## **Side effects**

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### **Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine.**

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

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

**Ask your doctor or pharmacist to answer any questions you may have.**

### **Tell your doctor if you notice any of the following and they worry you:**

- headache
- tiredness, low energy, difficulty sleeping
- feeling faint, light-headed, dizzy
- nervousness, anxiety
- nausea, vomiting, diarrhoea, upset stomach, feeling uncomfortable after eating, constipation
- muscle pain, cramp,
- changes in libido
- dry mouth
- increased blood sugar levels

The above list includes the more common side effects of your medicine.

### **Tell your doctor as soon as possible if you notice any of the following:**

- vertigo
- tinnitus (pain or ringing in the ears)
- signs of dehydration, such as increased thirst, dry mouth, tiredness, reduced urination
- tingling or numbness of the hands or feet
- gout (painful red, swollen joints)
- skin rash, itching
- increased sensitivity to sunlight or sunburn following only a small exposure to the sun
- frequent urge to urinate, pain when urinating, cloudy or bloody urine (signs of cystitis)
- fainting or passing out
- visual disturbances, blurred or changed vision
- excessive urination or sweating

The above list includes the more serious side effects of your medicine, which may require medical attention.

### **If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- dry mouth, thirst, weakness, fatigue, lethargy, drowsiness, restlessness, muscle pains or cramps, low blood pressure, low urine output, stomach upsets, nausea or irregular heart beat (signs of imbalanced electrolytes (salt) levels in the blood)
- fever, painful red or purplish rash that blisters (signs of Stevens-Johnson Syndrome or toxic epidermal necrolysis)
- severe abdominal pain, nausea, vomiting, fever (signs of pancreatitis)
- difficulty thinking, poor concentration, confusion, drowsiness, confused speech (signs of hepatic encephalopathy)

- fatigue, flu-like symptoms, dark urine, pale stools, abdominal pain, yellow skin and eyes (signs of hepatitis)
- worsening of symptoms if you suffer from systemic lupus erythematosus (a type of collagen disease)
- bruising or bleeding more easily (signs of thrombocytopenia)
- unexplained fever, soreness of the throat or other flu-like symptoms (signs of leukopenia)
- weakness, tiredness, shortness of breath, paleness (signs of anaemia)
- fast or irregular heartbeat, chest pain
- reduced amount of urine; swelling of your legs, ankles, and feet from retention of fluids (signs of kidney disease)
- including 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

The above list includes very serious side effects and you may need urgent medical attention or hospitalisation.

### **Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.**

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

Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

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## **Storage and disposal**

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### **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.**

### ***Sponsor***

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## **Product description**

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### ***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
- titanium dioxide
- purified talc

This medicine does not contain gluten.