

Insig tablets

Indapamide hemihydrate tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Insig.

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

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

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What Insig is used for

Insig belongs to a group of medicines called diuretics. It is used either alone or with other medicines to treat:

- mild to moderate hypertension (high blood pressure).

Everyone has blood pressure. This pressure helps get your blood all around your body. Your blood pressure may be different at different times of the day, depending on how busy or worried 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.

There are usually no symptoms of high blood pressure. The only way of knowing that you have it is to have your blood pressure checked on a regular basis.

Insig allows the heart muscle and surrounding blood vessels to relax more fully and hence carry the same volume of blood more easily. It can be used alone or in combination with other medicines to lower blood pressure.

Your doctor, however, may prescribe Insig for another purpose. Ask your doctor if you have any questions about why Insig has been prescribed for you.

Ask your doctor if you have any questions about why 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.

There is no known evidence to show that this medicine is addictive.

Use in children

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

Before You Take Insig

When you must not take Insig

Do not take this medicine if:

You have or have had any of the following:

- severe renal failure

- severe liver disease or suffer from a condition called hepatic encephalopathy (liver problems which affect the brain and central nervous system)
- a condition called anuria where there is a very low production of urine
- very low potassium levels in your blood
- You are taking any medications that could increase the risk of Torsades de pointes such as, chlorpromazine, thioridazine, trifluoperazine, amisulpride, droperidol, haloperidol, pimozide, astemizole, erythromycin IV, pentamidine, terfenadine, moxifloxacin, diphemanil, methadone and lithium.
- It has passed the expiry date (EXP) printed on the pack.
- The packaging is torn, shows signs of tampering or it does not look quite right.
- You are hypersensitive to, or have had an allergic reaction to indapamide, other sulphonamide or any of the ingredients listed at the end of this leaflet.

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, itching or hives on the skin.

If you think you are having an allergic reaction, contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

People who are in a coma should not be given this medicine.

Do not take this medicine if

you are intolerant or allergic to lactose.

This medicine contains lactose.

Before you start to take INSIG

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you are pregnant or plan to become pregnant.

It is not known how Insig may affect your developing baby if you take it during pregnancy. Your doctor will discuss the risks and benefits of taking Insig during pregnancy.

Tell your doctor if you are breastfeeding or wish to breastfeed.

Taking Indapamide is not advisable, as it can cross into breast milk. Your doctor will discuss with you the benefits and risks of taking this medicine whilst breast-feeding.

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

- liver problems
- kidney problems
- gout
- diabetes
- SLE (systemic lupus erythematosus)- a disease affecting the skin, joints and kidneys
- 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.

Tell your doctor if:

- you are planning to have surgery,
- if you are currently receiving or planning to receive dental treatment.
- You drink alcohol or you

are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy 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:

- certain medicines for treating psychoses: chlorpromazine, thioridazine, trifluoperazine,
- amisulpride, droperidol, haloperidol and pimozide
- lithium, a medicine used to treat mood swings and some types of depression
- certain antihistamines: astemizole and terfenadine
- erythromycin, an antibiotic (when given via injection or infusion); pentamidine and moxifloxacin
- diphemanil
- strong pain killers (narcotics), including and methadone

Some medicines may also interact with indapamide. These include:

- medicines known as barbiturates, used as sedatives or for treating epilepsy
- diuretic (fluid) tablets, for treating excess fluid and high blood pressure
- other medicines used to treat high blood pressure, such as ACE inhibitors or Angiotensin II receptor blockers
- medicines used to treat heart problems, such as digoxin, quinidine, disopyramide, amiodarone and sotalol

- tetracosactide, used for diagnosing some illnesses
- stimulant laxatives containing, for example, bisacodyl or senna
- some anti-inflammatory drugs such as steroid medicines and non-steroidal anti-inflammatory medicines (including high-dose aspirin)
- metformin tablets, used for treating diabetes
- calcium supplements or medicines containing calcium
- cyclosporin, taken by people who have had organ transplants or who have auto-immune disease or cancer
- baclofen, a muscle relaxant
- medicines containing iodine, which are used to diagnose certain medical conditions
- medicines which can affect the amount of indapamide which is broken down by the liver enzymes CYP2C9 and CYP3A4, such as ritonavir, ketoconazole, rifampicin phenytoin, imipramine and carbamazepine.

Taking strong painkillers, barbiturates or blood pressure tablets or drinking alcohol whilst taking this medicine may cause your blood pressure to drop too much and you may feel faint or pass out.

You may also develop serious kidney problems if you take a combination of diuretic tablets, other medicines for blood pressure, and non-steroidal anti-inflammatory drugs.

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

Other medicine not listed above may also interact with indapamide.

Alcohol should also be

avoided whilst taking indapamide.

How to take this medicine

Follow all directions given to you by your doctor or pharmacist carefully. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor or pharmacist will tell you how much of this medicine you should take. This will depend on your condition and whether or not you are taking any other medicines.

The usual dose is one tablet daily.

How to take it

Swallow the tablets with a glass of water.

When to take it

Take the tablet in the morning.

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.

It does not matter if you take it before, with or after food.

How long to take it for

Indapamide can help to control your blood pressure but cannot cure it, so you should keep taking your medicine for as long as your doctor tells you.

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, skip the missed dose

and take your next dose at the usual time.

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

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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 the nearest hospital, if you think you or anyone else may have taken too much Insig. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much indapamide, you may have nausea, vomiting, weakness, reduced breathing, fainting, dizziness, stomach upsets and/or electrolyte (salt) imbalance (feeling thirsty, weak, drowsy, restless, sick, or have weak or cramped muscles, or changes in your heart rate or rhythm).

While you are taking Insig

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you become pregnant or

plan to breastfeed

- you are about to have any blood tests
- you are going to have surgery.

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking indapamide.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

Indapamide affects the levels of potassium, chloride and sodium in the blood. Your doctor may conduct blood tests to monitor levels of these salts before and during your treatment. This is especially important for patients, who are at high risk of developing electrolyte disturbances (such as elderly, patients who are taking many medicines or patients who are malnourished).

Make sure you drink plenty of water in hot weather and during exercise, especially if you are sweating a lot. Not drinking enough water could cause a sudden drop in blood pressure.

Also make sure you tell your doctor if you become sick and have severe or continuing vomiting or diarrhoea while taking indapamide.

The loss of additional water and certain salts such as potassium from the body may make you feel faint, lightheaded, weak or dizzy.

Indapamide may increase the sensitivity of your skin to sunlight.

If taking indapamide, protect your skin from the sun or artificial UV light. If you develop severe sunburn after being in the sun, tell your doctor, who may tell you to stop taking your medicine.

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 or pharmacist tells you to
- Stop taking your medicine, or change the dosage, without first checking with your doctor

Things to be careful of

Be careful while driving or operating machinery until you know how indapamide affects you.

Indapamide may cause dizziness or drowsiness. Do not drive or operate machinery if indapamide affects you in this way.

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

Be careful getting up from a lying or sitting position. Get up slowly. Getting up too fast may cause a feeling of light-headedness, dizziness or fainting.

Side Effects

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

Do not be alarmed by the following list of side effects. You may not experience any of them. All medicines have side effects. Sometimes they are serious, but most of the time they are not.

Insig helps most people with high blood pressure, but it may have unwanted side effects in

some people.

Tell your doctor or pharmacist if you notice any of the following:

- feeling tired or weak or as if you have less energy
- nausea, vomiting, diarrhoea, constipation or stomach ache
- dry mouth
- muscle pain or cramps
- headache
- dizziness, giddiness or light-headedness, especially when getting up from a sitting or lying position
- tinnitus (pain or ringing in the ears), problems with your eyesight
- gout (painful red, swollen joints)
- change in libido
- sleepiness, problems sleeping
- increased blood sugar levels

Tell your doctor as soon as possible if you notice any of the following. These may be

serious side effects. You may need medical attention. Most of these side effects are rare.

- skin rash
- itching
- sunburn following only a small exposure to the sun
- joint or back pain
- weak legs
- excessive urination or sweating

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to Accident and Emergency at the nearest hospital. These are serious side effects. You may need urgent medical attention or hospitalisation.

- fast or irregular heartbeat
 - fainting or passing out
- symptoms of an imbalance of the electrolyte (salt) levels in the blood: 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. This is more likely if you are vomiting a lot, are on a drip, have heart failure, poor kidney or liver function, or are on a salt restricted diet.

- skin rash made up of purple spots, with occasional blisters - most often found on the front of the arms and legs, neck and around the ears, very rarely, accompanied by a fever. These are signs of something called Stevens Johnson Syndrome. This syndrome is very rare, but potentially very 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, 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, or other parts of the body
- rash, itching or hives on the skin
- fainting
- hayfever-like symptoms

After taking it

Storage

Keep Insig 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.

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

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

Keep your tablets in a cool dry place where the temperature will stay below 25 degrees Celsius.

Do not store Insig or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor or pharmacist 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

What it looks like

Insig 2.5 mg tablets (AUST R 184244) are presented in PVC/PVDC/Al blister packs of 60 or 90 tablets.

They are white, biconvex, sugar coated tablets.

Ingredients

Active Ingredient:

Indapamide hemihydrate

Each tablet contains 2.5 mg of Indapamide hemihydrate.

Other Ingredients:

- acacia
- calcium carbonate
- lactose monohydrate
- magnesium stearate
- OPAGLOS tablet core sealant product OPAGLOS 6000P OFF WHITE
- OPASEAL Pharmaceutical Enteric – Phthalavin (Pvap)

solution P-2-0300G Clear

- Povidone
- Maize starch
- Sucrose
- Purified Talc
- Titanium Dioxide

Please read this leaflet carefully before you start taking Insig. You may wish to keep it to read again.

Name and Address of the supplier

Arrow Pharma Pty Ltd
15 – 17 Chapel street, Cremorne
Victoria 3121
Australia

Date of Preparation

April 2020