

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking INSIG?

INSIG contains the active ingredient indapamide hemihydrate active ingredient indapamide which belongs to a group of medicines called chlorosulfamoyl diuretics (a type of “fluid” or “water” tablet). INSIG is used to treat high blood pressure (also known as hypertension).

For more information, see Section [1. Why am I taking INSIG?](#) in the full CMI.

2. What should I know before I take INSIG?

Do not take if you have ever had an allergic reaction to indapamide hemihydrate or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I take INSIG?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with indapamide and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take INSIG?

- Swallow tablet(s) with a glass of water. Do not crush or chew the tablets.

More instructions can be found in Section [4. How do I take INSIG?](#) in the full CMI.

5. What should I know while taking INSIG?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit 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 immediately if you notice any serious side effects, especially severe nausea or vomiting or stomach pain.
Things you should not do	<ul style="list-style-type: none">• Do not give this medicine to anyone else, even if they have the same condition as you.• Do not take this medicine to treat other complaints unless your doctor tells you to.• Do not stop taking this medicine or change the dosage, without checking with your doctor.• Is not recommended for use in children.
Driving or using machines	<ul style="list-style-type: none">• Take care when driving or operating machinery until you know how this medicine affects you.• Dizziness or weakness due to low blood pressure may occur in certain patients. If you have any of these symptoms do not drive or operate machinery.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol. Be careful when drinking alcohol while you are taking this medicine. Dizziness or light-headedness may be worse if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Store below 25°C. Store in original carton. Keep your tablets in the blister pack until it is time to take them.

For more information, see Section [5. What should I know while taking INSIG?](#) in the full CMI.

6. Are there any side effects?

There are a number of side effects associated with INSIG. It is important to be aware of them so that you can identify any symptoms if they occur.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

INSIG

Active ingredient(s): *indapamide hemihydrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking INSIG. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking INSIG.**

Where to find information in this leaflet:

- [1. Why am I taking INSIG](#)
- [2. What should I know before I take INSIG?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take INSIG?](#)
- [5. What should I know while taking INSIG?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking INSIG?

INSIG contains the active ingredients indapamide hemihydrate.

INSIG is used to treat high blood pressure (also known as hypertension).

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 (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.

INSIG helps to lower your blood pressure.

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.

There is no evidence that this medicine is addictive.

2. What should I know before I take INSIG?

Warnings

Do not take INSIG if:

You have or have had any of the following medical conditions:

- You are allergic to indapamide hemihydrate, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- Sulphonamide (sulfa) antibiotics, thiazide diuretics (a type of "fluid" or "water" tablet).
- You are intolerant or allergic to lactose. This medicine contains lactose.
- You have or have had any of the following medical conditions:
 - 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.
 - You are pregnant or trying to become pregnant. This medicine may affect your developing baby if you take it during pregnancy.
 - You are breastfeeding or intend to breastfeed. This medicine may pass into human breast milk.
- 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.

Tell your doctor straight away if:

- You have an intolerance to lactose monohydrate.
- 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.
- 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 INSIG. 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.

- You are pregnant or plan to become pregnant or are breastfeeding. Do not take this medicine whilst pregnant or breastfeeding.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. [Are there any side effects?](#)

Pregnancy and breastfeeding

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

Do not take this medicine if you are breastfeeding or plan to breastfeed.

It is important to tell your doctor if you are pregnant or intend to become pregnant, or if you are breastfeeding or intend to breastfeed.

What if I am taking other medicines?

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

You should not take INSIG 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).

Some medicines may interfere with INSIG and affect how it works. These include:

- 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 antidepressants (e.g. tricyclic antidepressants, antipsychotic drugs, neuroleptics such as: droperidol, haloperidol, chlorpromazine, trifluoperazine, amisulpride, sulpiride, psychoanaleptics e.g. donepezil).
- 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).
- Anaesthetics (e.g. propofol, sevoflurane).
- 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).
- Ciclosporin, 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 (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).

- These medicines may be affected by INSIG or may affect how well it works.

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 interfere with INSIG.

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

4. How do I take INSIG?

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.

When to take INSIG

Take it at about the same time each day, preferably in the morning. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

How to take INSIG

Swallow your tablet(s) with a glass of water. Do not crush or break the tablets.

If you forget to take INSIG

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

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 you experiencing side effects.

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

How long to take it

INSIG can help to control your blood pressure but cannot cure this condition. INSIG treatment is usually for life, 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 take too much INSIG

If you think that you have taken too much INSIG, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

If you take too much INSIG, your blood pressure may drop (hypotension) or you may be sick, feel confused, or have kidney problems or changes in the salt and water content of your body or muscle cramps. You may require urgent medical attention.

5. What should I know while taking INSIG?

Things you should do

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

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

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

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

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

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

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

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.

Call your doctor straight away if you:

- Notice any serious side effects, especially severe nausea or vomiting or stomach pain.

Remind any doctor, dentist or pharmacist you visit that you are taking INSIG.

Things you should not do

- Do not take this medicine 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 change the dosage without checking with your doctor.

Driving or using machines

Be careful when driving or operating machinery until you know how this medicine affects you. Dizziness or weakness due to low blood pressure may occur in certain patients. If you have any of these symptoms do not drive or operate machinery.

Drinking alcohol

Tell your doctor if you drink alcohol.

Be careful when drinking alcohol while you are taking this medicine. Dizziness or light-headedness may be worse if you drink alcohol.

Things to be careful of

You may feel light-headed or dizzy when you begin to take this medicine. This is because your blood pressure is falling. 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. If you have these symptoms and they do not get better in a short time, then talk to your doctor.

INSIG contains a drug substance which may give a positive result in doping tests.

Looking after your medicine

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. A locked cupboard at least one-and-a-half meters above ground is a good place to store medicines. Heat and dampness can destroy some medicines.

Follow the instructions on the carton on how to take care of your medicine properly.

Keep your medicine in a cool dry place where the temperature will stay below 25°C. Do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

When to discard your medicine

Do not take this medicine after the expiry date.

Getting rid of any unwanted medicine

If your doctor tells you to stop taking INSIG, or the tablets have passed their expiry date, return any leftover tablets to your pharmacist for disposal.

Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

INSIG helps most people with high blood pressure, but it may sometimes have unwanted side effects in a few people. While these side effects when they occur are usually mild they can be serious.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • 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 weakness, pain, tenderness, back pain, joint pain, cramp or 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. 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

<ul style="list-style-type: none"> • 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. 	
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Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• 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.	STOP TAKING THIS MEDICINE. Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

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, 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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

Product details

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

What INSIG contains

Active ingredient (main ingredient)	<ul style="list-style-type: none">• Each tablet contains 2.5 mg of indapamide hemihydrate.
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• acasia• calcium carbonate• lactose monohydrate• magnesium stearate• maize starch• povidone• purified talc• sucrose• titanium dioxide• OPAGLOS tablet core sealant product OPAGLOS 6000P OFF-WHITE• OPASEAL Pharmaceutical Enteric - Phthalavin (Pvap) Solution P-2-0300G Clear
Potential allergens	<ul style="list-style-type: none">• Lactose

This medicine is free from gluten, sucrose, tartrazine and other azo dyes.

Do not take this medicine if you are allergic to any of these ingredients.

What INSIG looks like

White, biconvex, sugar-coated tablets.

AUST R 184244.

Available in blister packs of 60 or 90 tablets.

Who distributes INSIG

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel St

Cremorne VIC 3121

www.arrotex.com.au

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