#### **Consumer Medicine Information**

#### What is in this leaflet

This leaflet answers some common questions about INSIG. 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 risk of you taking this medicine against the benefits they expect 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 need to read it again.

#### What INSIG is used for

INSIG is a diuretic (fluid tablet) that is used to treat mild to moderate hypertension (high blood pressure).

This medicine works by allowing the heart muscle and surrounding blood vessels to relax more fully and hence, carry the same volume of blood more easily.

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

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

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

#### Before you take INSIG

#### When you must not take it

### Do not take INSIG if you have an allergy to:

- any medicine containing indapamide hemihydrate
- · other sulphonamide-derived agents
- 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 or other parts of the body; rash, itching or hives on the skin.

## Do not take this medicine if you are pregnant.

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

### Do not breast-feed if you are taking this medicine.

It is not known if the active ingredient in INSIG passes into the breast milk and there is a possibility that your baby may be affected.

## **Do not give this medicine to children.**Safety and effectiveness in children have not

Safety and effectiveness in children have no been established.

#### Do not take this medicine after the expiry date printed on the pack or if 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 any allergies to any other medicines, foods, preservatives, or dyes.

INSIG can cause imbalance of the electrolyte levels in the blood. This is more likely to occur if you are:

- · vomiting a lot
- · on a drip
- · have heart failure
- · poor kidney or liver function
- · are on a salt restricted diet.

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

- · systematic lupus erythematosus
- gout
- · dry mouth
- thirst
- · weakness
- · fatigue
- lethargy
- drowsiness
- restlessness
- · muscle pains or cramps
- · low blood pressure
- · low urine output
- · stomach upsets
- · irregular heartbeat.

# Tell your doctor if you are pregnant or intend to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

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

#### Taking other medicines

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

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

- digoxin
- lithium, INSIG can increase the side effects of lithium
- · strong pain killers
- medicines to treat high blood pressure.

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

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

#### How to take INSIG

## Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions in this leaflet, ask your doctor or pharmacist for help.

#### How much to take

The recommended dose of INSIG is one 2.5mg tablet, taken in the morning.

#### How to take it

Swallow the tablets whole with a glass of water

When to take it

## Take your medicine at the same time each day in the morning.

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

If does not matter if you take this medicine before or after food.

#### How long to take it

### 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

## Continue taking your medicine until you finish the pack.

If you forget to take it

If it is almost time for your next dose, 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 the dose that you missed.

This may increase the chance of you getting 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 the nearest hospital, if you think that 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.

#### While you are using INSIG

#### Things you must do

If you are about to start on any new medicine, remind your doctor and pharmacist that you are taking INSIG.

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

If you are going to have surgery, tell your surgeon or anesthetist that you are taking this medicine.

It may affect other medicines used in the surgery.

If you become pregnant 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 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.

#### Things you must not do

Do not take INSIG 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 lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects. If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

#### Things to be careful of

### Be careful driving or operating machinery until you know how INSIG affects you.

This medicine may cause dizziness or drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

#### If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to you doctor.

#### Side effects

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

This medicine helps most people with mild to moderate hypertension, but if may have unwanted side effects in some people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Side effects caused by INSIG are usually mild and do not last for long periods of time.

Do not be alarmed by the following list 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 or pharmacist if you notice any of the following and they worry you:

- weakness
- headache
- stomach upsets

The above list includes the more common side effects of your medicine. They are usually mild and short lived.

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

- · fast or irregular heartbeat
- skin rash
- itching

The above list includes serious side effects which may require medical attention. Serious side effects are rare.

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

Other side effects not listed above may also occur in some people.

#### After using INSIG

#### 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 as well.

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

Do not store INSIG 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

#### Keep it 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

INSIG tablets are pink, circular, biconvex tablets with 'n' engraved on one side.

#### Ingredients

INSIG contains 2.5mg of indapamide hemihydrate as the active ingredient. It also contains:

- · lactose monohydrate
- · microcrystalline cellulose
- · maize starch
- · magnesium stearate
- · hypromellose
- sodium lauryl sulfate
- · opadry pink OY6925

The medicine does not contain sucrose, gluten, tartrazine, or any other azo dyes.

#### Supplier

INSIG is supplied in Australia by:

Arrow Pharma Pty Ltd 15 – 17 Chapel Street Cremorne VIC 3121

AUST R number 62057.

This leaflet was prepared in August 2017