INPLER

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I taking INPLER?

INPLER contains the active ingredient eplerenone. INPLER is used to treat heart failure in patients who have experienced a heart attack and to reduce the risk of death or need for hospitalisations due to heart failure in patients with chronic heart failure.

For more information, see Section 1. Why am I taking INPLER? in the full CMI.

2. What should I know before I take INPLER?

Do not take if you have ever had an allergic reaction to INPLER 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 INPLER? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with INPLER 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 INPLER?

- Your doctor will tell you how many tablets you need to take each day. The usual starting dose of INPLER is 25 mg taken once a day. More instructions can be found in Section 4. How do I take INPLER? in the full CMI.

5. What should I know while taking INPLER?

Things you should do	• Call your doctor straight away if you feel light-headed or dizzy after taking your first dose of INPLER, or when your dose is increased. • Make sure you drink enough water during exercise and hot weather when you are taking INPLER, especially if you sweat a lot. • Remind any doctor, dentist or pharmacist you visit that you are taking INPLER.
Things you should not do	• Do not stop taking your medicine, or lower the dosage, without checking with your doctor. • Do not take INPLER to treat any other complaints unless your doctor tells you to.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how INPLER affects you.
Looking after your medicine	• Keep your tablets in a cool dry place where the temperature stays below 25°C. • Do not store it in the bathroom or near a sink, or in the car or on window sills.

For more information, see Section 5. What should I know while taking INPLER? in the full CMI.

6. Are there any side effects?

Speak to your doctor if you have any of these less serious side effects and they worry you: feeling light-headed, dizzy or faint, stomach or bowel problems (e.g. feeling sick (nausea) or vomiting, diarrhoea, constipation, flatulence or wind), cough, sore throat, headache, rash, itchy skin, high temperature, signs of an infection, back pain.

Tell your doctor as soon as possible if you notice any of these serious side effects: heart flutters, increased heart rate, unusual tiredness, weakness, muscle spasms and pain, abdominal pain, enlargement of the breasts in men, reduced sense of touch, increased sweating, feeling weak and generally unwell, problems with sleeping.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of these very serious side effects: shortness of breath, swelling of the feet or legs due to fluid build up, chest pain which may spread to the neck and shoulders, swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.

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.

INPLER®

Active ingredient(s): *eplerenone*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking INPLER. **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 INPLER.**

Where to find information in this leaflet:

1. Why am I taking INPLER?
2. What should I know before I take INPLER?
3. What if I am taking other medicines?
4. How do I take INPLER?
5. What should I know while taking INPLER?
6. Are there any side effects?
7. Product details

1. Why am I taking INPLER?

INPLER contains the active ingredient eplerenone.

INPLER belongs to a group of medicines called 'selective aldosterone blockers' that stop the action of aldosterone.

- **INPLER is used to:**
- **treat heart failure in patients who have experienced a heart attack**
- **reduce the risk of death or need for hospitalisations due to heart failure in patients with chronic heart failure.**

A heart attack occurs when one of the major blood vessels supplying blood to your heart becomes blocked. This means that your heart cannot receive the oxygen it needs and becomes damaged. This may lead to further problems, such as heart failure, irregular heart rhythms and blood clots.

Heart failure means that the heart muscle is weak and cannot pump blood strongly enough to supply all the blood needed throughout the body. Heart failure is not the same as heart attack, and may start off with mild or no symptoms, but as the condition progresses, patients may feel short of breath or may get tired easily after light physical activity such as walking. Some patients may wake up short of breath at night, or have to prop their heads up during sleep to avoid this problem. Fluid may collect in different parts of the body, often first noticed as swollen ankles and feet.

How INPLER works

Your body makes a substance called aldosterone. It is important for regulating blood pressure and is one of the factors involved in heart function. Sometimes aldosterone can cause changes in our body that lead to heart failure. INPLER works by blocking the action of aldosterone, and slowing the progression of heart failure by reducing heart damage.

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.

There is no evidence that this medicine is addictive.

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

Use in children

The safety and effectiveness of INPLER in children have not been established.

2. What should I know before I take INPLER?

Warnings

Do not take INPLER if:

- you are allergic to eplerenone, or any of the ingredients listed at the end of this leaflet.
  Some of the symptoms of an allergic reaction may include:
  - skin rash
  - itchiness
  - shortness of breath
  - swelling of the face, lips or tongue
  - muscle pain or tenderness
  - joint pain

Always check the ingredients to make sure you can take this medicine.

- you have or have had any of the following medical conditions:
  - very high levels of potassium in your blood
  - severely reduced kidney function. Your doctor will determine your kidney function
  - severe liver problems.
- you are currently taking any of the following medicines:
  - potassium-sparing diuretics (e.g. spironolactone, amiloride), used to help the kidneys get rid of salt and water by increasing the amount of urine produced
  - ketoconazole and itraconazole used to treat fungal infections
  - clarithromycin, used to treat bacterial infections
  - saquinavir, ritonavir, for the treatment of HIV infections.

Taking INPLER together with the above medicines can lead to serious side effects.

- you are pregnant
- you are breast-feeding.

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.

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes
- take any medicines for any other conditions
- have or have had any of the following medical conditions:
    - high levels of potassium in your blood
    - diabetes
    - long term kidney disease
    - liver problems.

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 INPLER if you are pregnant.

Check with your doctor if you are pregnant or intend to become pregnant.

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

Do not breast-feed if you are taking INPLER.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

The active ingredient in INPLER may pass into breast milk and there is a possibility that your baby may be affected.

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 INPLER.

3. 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.

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

- Medicines known as angiotensin converting enzyme (ACE) inhibitor and/or angiotensin receptor blocker (ARB), such as quinapril, losartan. These are used to treat high blood pressure and some other heart conditions and may increase the risk of high potassium levels in your blood
- non-steroidal anti-inflammatory drugs (NSAIDs), medicines used to relieve pain, swelling and other symptoms of inflammation including aspirin and ibuprofen
- lithium, a medicine used to treat mood swings
- neuroleptics, used to treat certain mental illnesses
- tricyclic antidepressants, used to treat certain mental illnesses
- St John's Wort, used in the management of depression
- carbamazepine, used to control seizures, facial pain or certain types of mood disorders
- phenytoin and phenobarbital, medicines used to control seizures
- potassium-sparing diuretics, such as spironolactone, amiloride
- potassium supplements, or salt substitutes which contain potassium
- medicines used to treat fungal infections such as ketoconazole, itraconazole
- certain antibiotics used to treat bacterial infections, such as erythromycin, trimethoprim, rifampicin
- saquinavir, ritonavir, for the treatment of HIV infections
- immunosupressive agents such as ciclosporin, tacrolimus
- baclofen, a muscle relaxant
- prazosin, used to treat high blood pressure and other medical conditions
- alfuzosin, for the treatment of benign prostatic hyperplasia
- amifostine, used in combination with cancer treatments
- any other medicines used to treat high blood pressure or heart failure.

Some medicines may interfere with INPLER and affect how it works.

You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect INPLER.

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

4. How do I take INPLER?

How much to take

- Your doctor will tell you how many tablets you need to take each day. This may depend upon your age, your kidney condition, the potassium level in your blood, and whether or not you are taking any other medicines.
- The usual starting dose of INPLER is 25 mg taken once a day. After about 4 weeks, your doctor may increase the dose to 50 mg once a day.
- Follow the instructions provided by your doctor or pharmacist carefully and take INPLER until your doctor tells you to stop.

They may differ from the information contained in this leaflet.

- If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

When to take INPLER

- Take your medicine at about the same time each day.

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

- Your tablets may be taken with or after a meal, or on an empty stomach.

How to take INPLER

Swallow the tablets whole with a full glass of water.

How long to take INPLER

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.

If you forget to take INPLER

INPLER should be taken regularly at the same time each day.

If you miss your dose at the usual time, and it is less than 12 hours before your next dose, skip the dose you missed and take your next dose when you are meat 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 the dose you missed.

This may increase the chance of you getting an unwanted side effect.

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 INPLER

If you think that you or anyone else have taken too much INPLER, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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 INPLER, you may feel light-headed.

5. What should I know while taking INPLER?

Things you should do

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

Your doctor may occasionally do a blood test to check your potassium levels and see how your kidneys are working. Your dose of INPLER may be adjusted by your doctor, depending on the potassium levels in your blood.

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking INPLER.
- 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 while taking this medicine, tell your doctor that you are taking this medicine.
- Make sure you drink enough water during exercise and hot weather when you are taking this medicine, especially if you sweat a lot.

If you do not drink enough water while taking INPLER, you may feel faint, light-headed or sick. This is because your blood pressure is dropping suddenly. If you continue to feel unwell, tell your doctor.

- If you have excess vomiting or diarrhoea while taking INPLER, tell your doctor.

You may lose too much water and salt and your blood pressure may drop too much.

Call your doctor straight away if you:

- feel light-headed or dizzy after taking your first dose of INPLER, or when your dose is increased.

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

Things you should not do

- Do not take INPLER 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how INPLER affects you.

Looking after your medicine

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

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

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

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

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

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

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking INPLER or your condition changes. Tell your doctor even if you think the problem is not connected with the medicine or is not listed in this leaflet.

INPLER helps most people with heart failure, but it may have unwanted side effects in some people.

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.

It is often difficult to tell whether side effects are the result of taking INPLER, or the effects of your heart failure or side effects of other medicines you may be taking. For this reason it is important to report any change in your condition. Your doctor may want to change your dose or advise you to stop taking INPLER.

If you are over 65 years of age you may have an increased chance of having some side effects, as you may be more sensitive to the effects of the medication.

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

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

Less serious side effects

Less serious side effects	What to do

• Feeling light-headed, dizzy or faint
• Stomach or bowel problems
  o feeling sick (nausea) or vomiting
  o diarrhoea
  o constipation
  o flatulence or wind
• cough
• sore throat
• headache
• rash, itchy skin
• high temperature, signs of an infection
• back pain
	Speak to your doctor if you have any of these less serious side effects.
	This list includes the more common or noticeable side effects of your medicine.

Serious side effects

Serious side effects	What to do
• heart flutters, increased heart rate • unusual tiredness, weakness • muscle spasms and pain • abdominal pain • enlargement of the breasts in men • reduced sense of touch • increased sweating • feeling weak and generally unwell • problems with sleeping	**Tell your doctor as soon as possible if you notice any of these serious side effects.** This list includes side effects that may require medical attention. Serious side effects are rare.

Very serious side effects

Very serious side effects	What to do
• shortness of breath, swelling of the feet or legs due to fluid build up • chest pain which may spread to the neck and shoulders • swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing	**Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of these very 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.

Some of these side effects (for example, changes in potassium levels, thyroid function, or cholesterol level) can only be found when your doctor does tests from time to time to check your progress.

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.

7. Product details

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

What INPLER contains

Active ingredient	• eplerenone 25 mg or 50 mg per tablet

(main ingredient)	
Other ingredients **(inactive ingredients)**	• lactose • microcrystalline cellulose • croscarmellose sodium • hypromellose • sodium lauryl sulfate • purified talc • magnesium stearate • titanium dioxide • macrogol 400 • polysorbate 80 • iron oxide yellow • iron oxide red.
Potential allergens	lactose

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

What INPLER looks like

Beige, round, biconvex tablets, debossed "25" on one side. (AUST R 231447)

Beige, round, biconvex tablets, debossed "50" on one side.

(AUST R 231453)

INPLER is available in blister packs of 20, 30, 60, 90, and 120 tablets.

Who distributes INPLER

Sponsor

Arrotex Pharmaceuticals Pty Ltd

15 – 17 Chapel Street

Cremorne VIC 3121

http://arrotex.com.au/

Distributor

INPLER is distributed in Australia by:

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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