# Arrow-Losartan potassium & Hydrochlorothiazide

### **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 using Arrow - Losartan potassium & Hydrochlorothiazide?

Arrow-Losartan potassium & Hydrochlorothiazide contains two active ingredients: losartan potassium and hydrochlorothiazide. It is used to lower high blood pressure, which doctors call hypertension. For more information, see Section 1. Why am I using Arrow - Losartan potassium & Hydrochlorothiazide? in the full CMI.

### 2. What should I know before I use Arrow - Losartan potassium & Hydrochlorothiazide?

Do not use if you have ever had an allergic reaction to Arrow-Losartan potassium & Hydrochlorothiazide 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 use Arrow - Losartan potassium & Hydrochlorothiazide? in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Arrow-Losartan potassium & Hydrochlorothiazide 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 use Arrow - Losartan potassium & Hydrochlorothiazide?

- Your doctor will tell you how many tablets you need to take each day.
- Swallow with a glass of water

More instructions can be found in Section 4. How do I use Arrow - Losartan potassium & Hydrochlorothiazide? in the full CMI.

## 5. What should I know while using Arrow - Losartan potassium & Hydrochlorothiazide?

Things you should do	<ul> <li>Remind any doctor, dentist or pharmacist you visit that you are using this medicine.</li> <li>Have your blood pressure checked when your doctor says, to make sure this medicine is working.</li> <li>Tell your doctor if you are pregnant or plan to become pregnant.</li> </ul>	
Things you should not do	Do not give Arrow-Losartan potassium & Hydrochlorothiazide to anyone else, even if they have the same condition as you	
Driving or using machines	Make sure you know how you react to this medicine before you drive a car, operate machinery, or do anything else that could be dangerous.	
Drinking alcohol	If you drink alcohol, or take strong pain killers or barbiturates, some side effects may be worse	
Looking after your medicine	Keep it in a cool dry place where the temperature stays below 25°C	

For more information, see Section <u>5. What should I know while using Arrow - Losartan potassium & Hydrochlorothiazide?</u> in the full CMI.

### 6. Are there any side effects?

There are a number of side effects associated with this medicine. Tell your doctor of pharmacist as soon as possible if you do not feel well while you are taking Arrow-Losartan potassium & Hydrochlorothiazide.

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.

# Arrow - Losartan potassium & Hydrochlorothiazide

Active ingredient(s): Losartan potassium and Hydrochlorothiazide

### **Consumer Medicine Information (CMI)**

This leaflet provides important information about using Arrow-Losartan potassium & Hydrochlorothiazide . You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Arrow-Losartan potassium & Hydrochlorothiazide.

#### Where to find information in this leaflet:

- 1. Why am I using Arrow Losartan potassium & Hydrochlorothiazide?
- 2. What should I know before I use Arrow Losartan potassium & Hydrochlorothiazide?
- 3. What if I am taking other medicines?
- 4. <u>How do I use Arrow Losartan potassium & Hydrochlorothiazide?</u>
- <u>5.</u> What should I know while using Arrow Losartan potassium & Hydrochlorothiazide?
- <u>6.</u> <u>Are there any side effects?</u>
- 7. Product details

# 1. Why am I using Arrow - Losartan potassium & Hydrochlorothiazide?

Arrow - Losartan potassium & Hydrochlorothiazide contains the active ingredients losartan potassium and hydrochlorothiazide.

Arrow-Losartan potassium & Hydrochlorothiazide is a combination of an angiotensin II receptor antagonist (losartan) and a diuretic (hydrochlorothiazide).

# Arrow-Losartan potassium & Hydrochlorothiazide is used to lower high blood pressure.

Losartan lowers blood pressure by specifically blocking a substance called angiotensin II.

Angiotensin II normally tightens your blood vessels.

The losartan ingredient in Arrow-Losartan potassium & Hydrochlorothiazide allows them to relax. Hydrochlorothiazide works by making your kidneys pass more water and salt.

Arrow-Losartan potassium & Hydrochlorothiazide lowers high blood pressure, which doctors call hypertension. It may be used alone or in combination with other medicines. In patients with high blood pressure and a thickening of the left ventricle, losartan, often in combination with hydrochlorothiazide, reduces the risk of stroke and heart attack and helps patients live longer.

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 hypertension (high blood pressure) when your blood pressure stays higher than is needed, even when you are calm and relaxed.

There are usually no symptoms of hypertension. The only way of knowing that you have hypertension is to have your blood pressure checked on a regular basis. If high blood pressure is not treated it can lead to serious health problems. You may feel fine and have no symptoms, but eventually hypertension can cause stroke, heart disease and kidney failure. Over time, high blood pressure causes the heart to work harder, which can lead to a thickening of the left ventricle. A thickening of the left ventricle of the heart is associated with an increased chance of experiencing a stroke.

Your doctor may have prescribed Arrow-Losartan potassium & Hydrochlorothiazide for another reason.

Arrow-Losartan potassium & Hydrochlorothiazide is not addictive.

## 2. What should I know before I use Arrow -Losartan potassium & Hydrochlorothiazide?

#### Warnings

# Do not use Arrow-Losartan potassium & Hydrochlorothiazide if:

- you are allergic to losartan, hydrochlorothiazide or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- you have an allergy to any sulphonamide or sulphur medicines. One of the ingredients in Arrow-Losartan potassium & Hydrochlorothiazide, hydrochlorothiazide, is a sulphur containing medicine (a sulphonamide). Therefore, if you are allergic to sulphur medicines, such as some antibiotics, you are likely to be allergic to Arrow Losartan potassium & Hydrochlorothiazide. Check with your doctor or pharmacist if you are not sure whether you are allergic to sulphur medicines.
- Symptoms of an allergic reaction may include skin rash, hives, fever, swelling of the face, lips, mouth, throat or tongue which may cause difficulty breathing or swallowing.
- You have experienced breathing or lung problems
   (including inflammation or fluid in the lungs) following
   hydrochlorothiazide intake in the past. If you develop
   any severe shortness of breath or difficulty breathing
   after taking Losartan potassium &
   Hydrochlorothiazide, seek medical attention
   immediately.
- you are pregnant or breast-feeding. Your baby may absorb this medicine in the womb or from breast milk and therefore there is a possibility of harm to the baby.
- you are not passing urine.

- you have diabetes and are taking a medicine called aliskiren to reduce blood pressure.
- the packaging is torn or shows signs of tampering.
- the expiry date (EXP) printed on the pack has passed.
   If you take this medicine after the expiry date has passed, it may not work.

### Check with your doctor if you:

- intend to become pregnant or plan to breast-feed.
   Arrow-Losartan potassium & Hydrochlorothiazide is not recommended for use during pregnancy or while breast-feeding.
- have any other medical conditions especially the following: liver disease, kidney disease, diabetes, gout, lupus erythematosus (known as SLE), a disease affecting the skin, joints and kidneys, high cholesterol or triglyceride levels.
- have recently had excessive vomiting or diarrhoea
- if you have any allergies to any other medicines or any other substances, such as foods preservatives or dyes

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

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

The use of losartan is contraindicated during the 2nd and 3rd trimester of pregnancy. There is limited experience with hydrochlorothiazide during pregnancy, especially during the first trimester.

If you get pregnant while taking Arrow-Losartan potassium & Hydrochlorothiazide, treatment should be stopped immediately and, if appropriate, alternative therapy should be started.

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

Your baby may absorb this medicine in the womb or from breast milk and therefore there is a possibility of harm to the baby.

Hydrochlorothiazide is excreted in human milk in small amounts. Thiazides in high doses causing intense diuresis can inhibit the milk production. The use of this medicine during breastfeeding is not recommended.

### 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.

# Some medicines may interfere with Arrow-Losartan potassium & Hydrochlorothiazide and affect how it works. These include:

- other fluid tablets (diuretic), also called water tablets, including potassium-sparing diuretics
- potassium tablets

- potassium-containing salt substitutes
- other medicines used to treat high blood pressure
- digoxin, used to treat heart failure
- lithium, used to treat severe mood swings and some types of depression
- steroid medicines such as cortisone, prednisone and glycyrrhizin found in liquorice root
- insulin and tablets used to treat diabetes
- barbiturates, used to treat epilepsy, such as phenobarbitone
- strong pain killers such as codeine, morphine, dextroproxyphene
- non-steroidal anti-inflammatory medicines (NSAIDs) including cyclooxygenase- 2 inhibitors (COX-2) used to treat inflammation, pain, arthritis
- cholestyramine and colestipol, used to treat high cholesterol
- medicines used to relax muscles before and during surgery
- medicines used in emergency situations such as adrenaline
- alcohol

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Arrow - Losartan potassium & Hydrochlorothiazide.

# 4. How do I use Arrow - Losartan potassium & Hydrochlorothiazide?

#### How much to take

- Take Arrow-Losartan potassium &
   Hydrochlorothiazide only when prescribed by your
   doctor. Your doctor will tell you how many tablets you
   need to take each day. This depends on your condition
   and whether you are taking other medicines.
- For most patients, the usual dose is one tablet of Arrow-Losartan potassium & Hydrochlorothiazide once a day.
- Depending on your condition, the dose may need to be increased to two tablets of Arrow-Losartan potassium & Hydrochlorothiazide once a day.
- Follow the instructions provided and use Arrow-Losartan potassium & Hydrochlorothiazide until your doctor tells you to stop.

# When to take Arrow - Losartan potassium & Hydrochlorothiazide

 Arrow-Losartan potassium & Hydrochlorothiazide should be used at about the same time each day.
 Taking your tablet(s) at the same time each day will have the best effect. It will also help you remember when to take the tablet(s).

# How to take Arrow-Losartan potassium & Hydrochlorothiazide

Swallow Arrow-Losartan potassium &
 Hydrochlorothiazide with a glass of water. It does not

matter whether you take Arrow-Losartan potassium & Hydrochlorothiazide before or after food.

# If you forget to use Arrow - Losartan potassium & Hydrochlorothiazide

Arrow-Losartan potassium & Hydrochlorothiazide should be used regularly at the same time each day.

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

Do not take a double dose to make up for the dose you missed

# If you use too much Arrow - Losartan potassium & Hydrochlorothiazide

If you think that you have used too much Arrow - Losartan potassium & Hydrochlorothiazide, you may need urgent medical attention.

#### You should immediately:

- phone the National Poisons Centre (telephone 0800 POISON or 0800 764 766), 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.

## 5. What should I know while using Arrow -Losartan potassium & Hydrochlorothiazide?

### Things you should do

Tell your doctor immediately if you become pregnant while taking Arrow - Losartan potassium & Hydrochlorothiazide.

- Have your blood pressure checked when your doctor says, to make sure Arrow-Losartan potassium & Hydrochlorothiazide is working.
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Arrow-Losartan potassium & Hydrochlorothiazide.
- If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.
- You may feel light-headed or dizzy when you begin to take Arrow-Losartan potassium & Hydrochlorothiazide. This is because your blood pressure is falling suddenly. 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 gets worse or continues, talk to your doctor.
- Tell your doctor If you have excessive vomiting and/or diarrhoea while taking Arrow-Losartan potassium & Hydrochlorothiazide, or you have any of the following symptoms: dry mouth, thirst, weakness, tiredness, drowsiness, muscle pains or cramps, fast heart beat or passing less urine than normal. You may be

- dehydrated because you are losing too much water and your blood pressure may become too low.
- Make sure you drink enough water during exercise and hot weather when you are taking Arrow-Losartan potassium & Hydrochlorothiazide, especially if you sweat a lot. If you do not drink enough water while taking Arrow-Losartan potassium & Hydrochlorothiazide, you may faint or feel lightheaded or sick. This is because your body doesn't have enough fluid and your blood pressure is low. If you continue to feel unwell, tell your doctor.
- If you plan to have surgery (even at the dentist) that needs a general anaesthetic, tell your doctor or dentist that you are taking Arrow-Losartan potassium & Hydrochlorothiazide.
- Continue taking potassium tablets if your doctor has prescribed these for you. Arrow-Losartan potassium & Hydrochlorothiazide contains a very small amount of potassium, but this does not replace any potassium tablets that you may be taking.

Remind any doctor, dentist or pharmacist you visit that you are using Arrow - Losartan potassium & Hydrochlorothiazide.

### Things you should not do

 Do not give Arrow-Losartan potassium & Hydrochlorothiazide to anyone else, even if they have the same condition as you.

#### Driving or using machines

Be careful before you drive or use any machines or tools until you know how Arrow-Losartan potassium & Hydrochlorothiazide affects you.

Arrow-Losartan potassium & Hydrochlorothiazide may cause dizziness in some people.

### **Drinking alcohol**

### Tell your doctor if you drink alcohol.

If you drink alcohol, or take strong pain killers or barbiturates, the effects may be worse.

### Looking after your medicine

- Keep Arrow-Losartan potassium & Hydrochlorothiazide in a cool, dry place where the temperature stays below 25°C
- Keep your 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.

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.

#### Getting rid of any unwanted medicine

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

Do not use this medicine after the expiry date.

## 6. 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.

#### Less serious side effects

Less serious side effects	What to do	
Skin-related	Speak to your	
<ul> <li>rash</li> <li>dermatitis</li> <li>increased sensitivity of the skin to sun</li> <li>Digestive system-related</li> </ul>	doctor if you have any of these less serious side effects and they worry you.	
<ul> <li>nausea</li> <li>vomiting</li> <li>cramping</li> <li>constipation</li> <li>taste alteration</li> <li>diarrhoea</li> </ul>		
Respiratory system-related		
<ul><li>fatigue</li><li>cough</li></ul>		
Nervous system-related		
<ul> <li>restlessness</li> <li>headache</li> <li>weakness</li> <li>dizziness</li> <li>dizziness/light-headedness; due to a sudden drop in blood pressure when standing up quickly</li> </ul>		
Other		
<ul><li>transient blurred vision</li><li>yellowing of the skin and/or eyes, also called jaundice</li></ul>		

#### Serious side effects

Serious side effects	What to do
<ul> <li>Allergic reactions</li> <li>swelling of the face, lips, mouth, throat or tongue which may cause difficulty swallowing or breathing</li> <li>shortness of breath</li> <li>severe and sudden onset of pinkish, itchy swellings on the skin, also called hives or nettlerash</li> <li>severe skin reaction which starts with painful red areas, then large blisters and ends with peeling of layers of skin. This is accompanied by fever and chills, aching muscles and generally feeling unwell.</li> </ul>	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.
Respiratory system-related	
<ul> <li>Acute respiratory distress, signs include severe shortness of breath, fever, weakness and confusion.</li> </ul>	

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.

### **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to <a href="https://pophealth.my.site.com/carmreportnz/s/">https://pophealth.my.site.com/carmreportnz/s/</a>. 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 Arrow-Losartan potassium & Hydrochlorothiazide contains

Active ingredient	losartan potassium 50 mg
(main ingredient)	hydrochlorothiazide 12.5 mg
Other ingredients	lactose monohydrate
(inactive ingredients)	microcrystalline cellulose
	pregelatinised starch
	maize starch
	colloidal anhydrous silica
	magnesium stearate

	hydroxyl propyl methyl cellulose
	titanium dioxide
	purified talc
	macrogol 6000
	quinoline yellow lake
	purified water
Potential allergens	Contains lactose

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

### What Arrow-Losartan potassium & Hydrochlorothiazide looks like

Arrow-Losartan potassium & Hydrochlorothiazide tablets are yellow coloured, oval shaped, biconvex, film-coated tablets.

# Who distributes Arrow - Losartan Potassium & Hydrochlorothiazide

Teva Pharma (New Zealand) Limited PO Box 128 244 Remuera Auckland 1541

Telephone: 0800 800 097

This leaflet was prepared in September 2024.