# PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS:** S3

**ARNIZYD 26/24 film-coated tablets**

**ARNIZYD 51/49 film-coated tablets**

**ARNIZYD 103/97 film-coated tablets**

**Valsartan / sacubitril**

**Sugar free.**

**Read all of this leaflet carefully before you start taking ARNIZYD.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care provider.
- ARNIZYD has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

**What is in this leaflet**

1. What ARNIZYD is and what it is used for
2. What you need to know before you take ARNIZYD
3. How to take ARNIZYD
4. Possible side effects
5. How to store ARNIZYD
6. Contents of the pack and other information.

## 1. What ARNIZYD is and what it is used for

ARNIZYD is a medicine containing an angiotensin receptor neprilysin inhibitor. It delivers two active substances, sacubitril and valsartan.

ARNIZYD is used to treat a type of long-term heart failure in adults.

This type of heart failure occurs when the heart is weak and cannot pump enough blood to the lungs and the rest of the body. The most common symptoms of heart failure are breathlessness, fatigue, tiredness and ankle swelling.

## 2. What you need to know before you take ARNIZYD

**Do not take ARNIZYD:**

- If you are hypersensitive (allergic) to sacubitril, valsartan or any of the other ingredients of ARNIZYD listed in section 6 of this leaflet.
- If you are taking another type of medicine called an angiotensin-converting enzyme (ACE) inhibitor. ACE inhibitors are used to treat high blood pressure or heart failure. If you have been taking an ACE inhibitor, wait for 36 hours after taking the last dose before you start to take ARNIZYD (see **Other medicines and ARNIZYD**).
- If you or a member of your family have ever had a reaction called angioedema (swelling of the face, lips, tongue and/or throat, difficulties in breathing) when taking an ACE inhibitor or an angiotensin receptor blocker (ARB) (such as valsartan, telmisartan or irbesartan).
- If you have hypertrophic obstructive cardiomyopathy (HOCM) (a heart disease characterised by the obstruction of blood flow and thickening of heart tissue).
- If you have renal artery stenosis (kidney problems with reduced blood supply to your kidney).
- If you have aortic stenosis (a decrease in blood supply through the aortic artery).
- If you are using any of the following medicine (see **Other medicines and ARNIZYD**):
  - Potassium-sparing diuretics, such as spironolactone, triamterene, amiloride (used to remove excess fluid from your body).
  - Lithium (used to treat some types of depression).
- If you have porphyria (a rare hereditary disease in which there is an abnormal metabolism of the blood pigment haemoglobin in your blood).
- If you are being treated with a blood pressure-lowering medicine containing aliskiren.
- If you have severe kidney problems.

- If you have severe liver problems or bile problems such as biliary cirrhosis or cholestasis.
- If you are pregnant or breastfeeding (see **Pregnancy, breastfeeding and fertility**).
- If you are taking medicines called renin antagonists, such as aliskiren.

**Warnings and precautions**

**If you are female and you become pregnant while taking ARNIZYD, tell your doctor immediately. Your doctor will stop your treatment with ARNIZYD and switch you to a different class of antihypertensive medicine (used to treat high blood pressure).**

Tell your doctor or health care provider before taking ARNIZYD:

- If you are being treated with an angiotensin receptor blocker (ARB) or aliskiren (see **Do not take ARNIZYD**).
- If you have low blood pressure or are taking any other medicines that reduce your blood pressure (for example, a diuretic) or are suffering from vomiting or diarrhoea, especially if you are aged 65 years or more, or if you have kidney disease and low blood pressure.
- If you are dehydrated.
- If you have kidney problems.
- If you have diabetes.
- If you are on a high potassium diet.
- If you suffer from hyperaldosteronism (a disease in which your adrenal glands make too much of the hormone aldosterone).
- If you take diuretics (water pills) or potassium supplements.
- If you have liver problems.

Your doctor may check the amount of potassium in your blood at regular intervals during ARNIZYD treatment.

**Children and adolescents**

Do not give ARNIZYD to children and adolescents under the age of 18 years because it has not been studied in this age group.

**Other medicines and ARNIZYD**

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor or pharmacist if you are currently taking:

- ACE inhibitors (see **Do not take ARNIZYD**).
- Other medicines used to treat heart failure or lower blood pressure, such as angiotensin receptor blockers or aliskiren (see **Do not take ARNIZYD**).
- Some medicines known as statins that are used to lower high cholesterol levels (for example atorvastatin).
- Sildenafil (used to treat erectile dysfunction or lung hypertension).
- Medicines that increase the amount of potassium in the blood. These include potassium supplements, salt substitutes containing potassium, potassium-sparing medicines and heparin.
- Painkillers of the type called non-steroidal anti-inflammatory medicines (NSAIDs) or selective cyclooxygenase-2 (Cox-2) inhibitors. If you are taking one of these, your doctor may want to check your kidney function when starting or adjusting treatment.
- Lithium (used to treat some types of depression) (see **Do not take ARNIZYD**).
- Furosemide (a diuretic which is used to increase the amount of urine you produce).
- Nitroglycerine (used to treat angina pectoris).
- Rifampicin (used to treat tuberculosis [TB]).
- Ciclosporin (used to prevent organ rejection after a transplant).
- Medicines used in the treatment of HIV (human immunodeficiency virus) and AIDS (acquired immune deficiency syndrome) (ritonavir, tenofovir, cidofovir).

- Metformin (used to treat diabetes).

**ARNIZYD with food, drink and alcohol**

See section 3.

**Pregnancy, breastfeeding and fertility**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking ARNIZYD.

Safety and efficacy of ARNIZYD during pregnancy and lactation have not been established. Do not use ARNIZYD if you are pregnant or breastfeeding.

**Driving and using machines**

ARNIZYD may cause dizziness and fatigue. Take special care before driving a vehicle or performing tasks that require your attention until you know how you will react to ARNIZYD.

## 3. How to take ARNIZYD

Do not share medicines prescribed for you with any other person.

Always take ARNIZYD exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

***Adults***

The usual recommended target dose is ARNIZYD 51/49 twice a day (one tablet in the morning and one tablet in the evening).

You will usually start by taking ARNIZYD 26/24 or ARNIZYD 51/49 twice a day.

Your doctor will decide your exact starting dose based on which medicines you have been taking previously. Your doctor will then adjust the dose depending on how you respond to the treatment

until the best dose for you is found.

Patients taking ARNIZYD can develop low blood pressure (dizziness, light-headedness), a high level of potassium in the blood (which would be detected when your doctor perform a blood test) or decreased kidney function. If this happens, your doctor may reduce the dose of any other medicine you are taking, temporarily reduce your ARNIZYD dose, or stop your ARNIZYD treatment completely.
Swallow the tablets with a glass of water. You can take ARNIZYD with or without food.

Your doctor will tell you how long your treatment with ARNIZYD will last.
If you have the impression that the effect of ARNIZYD is too strong or too weak, tell your doctor or pharmacist.

**If you take more ARNIZYD than you should**

If you have accidentally taken too many ARNIZYD tablets, you may experience severe dizziness. If this happens, you should lie down and contact your doctor. In the event of overdosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison centre. Take along any tablets that are left, including the carton, so that the hospital staff can easily tell what you have taken.

**If you forget to take ARNIZYD**

It is advisable to take your medicine at the same time each day. However, if you forget to take a dose, do not take a double dose to make up for a forgotten dose. Take the next dose as usual.

**If you stop taking ARNIZYD**

Stopping your treatment with ARNIZYD may cause your condition to get worse. Do not stop taking ARNIZYD unless your doctor tells you to.

## 4. Possible side effects

ARNIZYD can have side effects.

Not all side effects reported for ARNIZYD are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ARNIZYD, please consult your health care provider for advice.

If any of the following happens, stop taking ARNIZYD and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to ARNIZYD. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- kidney impairment including kidney failure (drowsiness, shortness of breath, fatigue, confusion, nausea, fits, passing less urine than is normal for you).

This is a serious side effect. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

*Frequent side effects:*

- anaemia (fatigue, loss of energy, pale skin, cramps in your legs, difficulty with concentration);
- too high or too low levels of potassium in your blood (abnormal or slow heart rate, low blood pressure, cramps, weakness);
- low sugar levels in your blood (sweating, weakness, hunger, dizziness, trembling, headache, flushing or paleness, numbness);

- headache, dizziness;
- vertigo (sensation of spinning or swaying);
- low blood pressure, dizziness upon standing up or sitting down;
- cough;
- diarrhoea, nausea (feeling sick), stomach pain;
- feeling tired, general feeling of weakness.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**Reporting of side effects:**

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA's website.

By reporting side effects, you can help provide more information on the safety of ARNIZYD.

## 5. How to store ARNIZYD

- Store at or below 25 °C.
- Protect from moisture.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton/blister.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

## 6. Contents of the pack and other information

**What ARNIZYD contains**

The active substances in ARNIZYD are sacubitril and valsartan.

ARNIZYD 26/24: Each film-coated tablet contains 24 mg sacubitril and 26 mg valsartan.

ARNIZYD 51/49: Each film-coated tablet contains 49 mg sacubitril and 51 mg valsartan.

ARNIZYD 103/97: Each film-coated tablet contains 97 mg sacubitril and 103 mg valsartan.

The other ingredients are colloidal silicon dioxide (E551), crospovidone (E1202), hydroxypropyl cellulose (E463), microcrystalline cellulose [E460(i)] and sodium stearyl fumarate.

ARNIZYD 26/24: Opadry White [containing hypromellose (E464), macrogol (E1521) and titanium dioxide (E171)].

ARNIZYD 51/49: Opadry Brown [containing hypromellose (E464), iron oxide black (E172), iron oxide red (E172), iron oxide yellow (E172), macrogol (E1521) and titanium dioxide (E171)].

ARNIZYD 103/97: Opadry Orange [containing FD&C Blue (E132), FD&C Red (E129), FD&C Yellow (E102), hypromellose (E464), macrogol (E1521) and titanium dioxide (E171)].

**What ARNIZYD looks like and contents of the pack**

ARNIZYD 26/24: White to off-white coloured, film-coated, oval shaped tablets debossed with “1272” on one side and plain on other side.

ARNIZYD 51/49: Brown to dark brown coloured, film-coated, oval shaped tablets debossed with “1273” on one side and plain on other side.

ARNIZYD 103/97: Light orange to orange coloured, film-coated, oval shaped tablets debossed with “1274” on one side and plain on other side.

Alu-OPA/MAF/PVC blister strips in a carton containing 30 or 60 tablets.

**Holder of certificate of registration**

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