

## **Package leaflet: Information for the user**

### **Aqumeldi 0.25 mg orodispersible tablets Aqumeldi 1 mg orodispersible tablets enalapril maleate**

**Read all of this leaflet carefully before you or your child starts taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your or your child's doctor or pharmacist.
- This medicine has been prescribed for you or your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours or your child's.
- If you or your child gets any side effects, talk to their doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

### **What is in this leaflet**

1. What Aqumeldi is and what it is used for
2. What you need to know before you or your child uses Aqumeldi
3. How to use Aqumeldi
4. Possible side effects
5. How to store Aqumeldi
6. Contents of the pack and other information

#### **1. What Aqumeldi is and what it is used for**

Aqumeldi contains the active substance enalapril maleate.

It is used in children and adolescents from birth to 17 years to treat heart failure (the inability of the heart to pump enough blood around the body).

Enalapril maleate belongs to a group of medicines called angiotensin converting enzyme inhibitors (ACE inhibitors), which means that it blocks an enzyme (protein) in the body from forming the hormone angiotensin II. By narrowing blood vessels, angiotensin II can cause high blood pressure which forces the heart to work harder to pump blood around the body. Angiotensin II also releases hormones, such as aldosterone, that raise blood pressure by causing fluid retention.

By blocking the formation of angiotensin II, Aqumeldi modifies the hormone system which influences blood pressure and fluid balance within the body. This helps to lower blood pressure and increases the supply of blood and oxygen to the heart. The medicine usually starts to work within an hour, but several weeks of treatment may be required before the condition improves.

#### **2. What you need to know before you or your child uses Aqumeldi**

##### **Do not give Aqumeldi if you or your child**

- is allergic to enalapril maleate, any of the other ingredients of this medicine (listed in section 6) or other ACE inhibitors (such as captopril, lisinopril or ramipril). ACE inhibitors are used to treat high blood pressure or heart failure).
- has ever had a reaction called angioedema (rapid swelling under the skin in areas such as the face, throat, arms and legs, which can be life threatening if throat swelling blocks the airway) when taking another ACE inhibitor or when the cause for angioedema was not-known or it was inherited.

- is more than 3 months pregnant. It is also better to avoid Aqumeldi in early pregnancy – (see section 2 “Pregnancy, breast-feeding and fertility”).
- has diabetes or reduced kidney function and is treated with a blood pressure lowering medicine containing aliskiren (see section 2 “Other medicines and Aqumeldi”).
- has taken or is currently taking sacubitril / valsartan, a medicine used to treat a type of long-term (chronic) heart failure, as the risk of angioedema is increased. Wait at least 36 hours after last dose of sacubitril / valsartan before taking Aqumeldi.
- has severe kidney disease.

If you are not sure, talk to your or your child’s doctor or pharmacist before giving Aqumeldi.

### **Warnings and precautions**

Talk to the doctor before giving Aqumeldi if you or your child:

- has a heart problem called left ventricular valvular obstruction or outflow tract obstruction or cardiogenic shock.
- has a condition involving the blood vessels in the brain (e.g., stenosis, thrombosis, embolism, haemorrhage).
- has collagen vascular disease (conditions that cause long-lasting inflammation in connective tissues which are tissues that hold your bones, muscles and ligaments together).
- is taking immunosuppressant therapy (used to lower the body’s immune response), treatment with allopurinol (used to lower uric acid levels) or procainamide (used to treat rhythm disturbances of the heart). In these instances, enalapril can increase the risk of low levels of neutrophils (neutropenia) a type of white blood cell that fights infection, very low levels of a type of white blood cell called granulocytes (agranulocytosis) which are important for fighting off infection, low levels of blood platelets (thrombocytopenia) which can lead to bleeding and bruising and low levels of red blood cells (anaemia) which can cause tiredness and pale skin (see section 2 “Other medicines and Aqumeldi”).
- has ever had an allergic reaction to ACE inhibitors, with swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing (angioedema). Angioedema can occur at any point during treatment with Aqumeldi. If symptoms appear Aqumeldi should be stopped and immediate treatment sought. You should be aware that black patients are at increased risk of these types of reactions to ACE inhibitors (medicines that work like Aqumeldi). The risk of angioedema may be increased in patients taking other medicines (see section 2 “Other medicines and Aqumeldi”).
- has a kidney problem (including kidney transplantation) diabetes, dehydration, sudden worsening of heart failure, a build up of acid in the body or use of diuretics (water tablets) which maintain the amount of potassium in the blood (such as spironolactone, eplerenone, triamterene, or amiloride) or substitutes that contain potassium or medicines known to increase potassium in the blood (such as, heparin, trimethoprim or cotrimoxazole). These situations may lead to high blood potassium levels (hyperkalaemia) which can cause tiredness, muscle weakness, feeling sick and heart rhythm disturbances. Your or your child’s doctor may need to adjust the dose of Aqumeldi or regularly check the amount of potassium in the blood (see section 2 “Other medicines and Aqumeldi”).
- has a problem with the arteries of the kidney, as this can increase the risk of low blood pressure or the kidneys not working properly.
- has been very sick (excessive vomiting) or had bad diarrhoea recently.
- has diabetes. The blood should be checked for low blood glucose levels, especially during the first month of treatment. The amount of potassium in the blood can also be higher.
- is having dialysis, since the dose of Aqumeldi may need changing.
- has low blood pressure (may be noticed as faintness or dizziness, especially when standing).
- is taking any of the following medicines used to treat high blood pressure: an angiotensin II receptor blocker (ARBs) (also known as sartans - for example valsartan, telmisartan, irbesartan) as these can increase the risk of low blood pressure, high potassium in the blood and kidney problems (see section 2 “Other medicines and Aqumeldi”).
- is under 1 month of age and has a liver problem or jaundice (yellowing of the skin and white of the eye).

- is under 1 month of age as very young children are more at risk of problems with low blood pressure, kidney problems and high potassium in the blood.

Your doctor may check your or your child's kidney function, blood pressure, and the level of electrolytes (e.g., potassium) in the blood regularly.

If you are not sure if any of the above apply to you or your child, talk to your doctor or pharmacist before giving Aqumeldi.

#### **If you or your child is about to have a medical procedure**

Tell the doctor that you or your child are using Aqumeldi if you or your child are about to receive any of the following procedures:

- any surgery or medicine to numb sensation (anaesthetic) (even at the dentist).
- desensitisation as a treatment for allergy, for example with bee or wasp venom (hymenoptera venom).
- treatment to remove cholesterol from the blood called LDL-apheresis.

If any of the above applies talk to your or your child's doctor or dentist before the procedure.

#### **Other medicines and Aqumeldi**

Please tell the doctor or pharmacist if you or your child is taking, has recently taken, or might take any other medicines including medicines obtained without a prescription. This includes herbal medicines. Your doctor may need to change your or your child's dose and/or to take other precautions.

Taking Aqumeldi with the following medicines can affect the way Aqumeldi or the listed medicines work or can increase the risk of side effects:

- **antihypertensives**, medicines to lower blood pressure (different types are listed below):
  - angiotensin II receptor blockers (ARBs), sometimes called sartans, (e.g. losartan, valsartan);
  - aliskiren;
  - beta blockers (e.g. atenolol, propranolol);
  - diuretics (a medicine that increases urine production) (e.g. furosemide, chlorothiazide);
  - vasodilators (medicine to open (dilate) blood vessels) (e.g. nitroglycerin, isosorbide mononitrate);
  - neprilysin inhibitors (e.g. sacubitril, racecadotril).
- The risk of angioedema (swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing) may be increased when using these medicines (see in section 2 "Do not give Aqumeldi if you or your child").
- **potassium preserving medicines**, medicines to increase potassium in the blood can cause the potassium to be too high) (different types are listed below):
  - potassium supplements and salt substitutes;
  - potassium-sparing diuretics (a medicine that increases urine production) (e.g. spironolactone, amiloride);
  - antibiotics, used to treat bacterial infections (e.g. trimethoprim and co-trimoxazole);
  - heparin used to thin blood and prevent clots.
- **lithium**, medicine to treat depression.
- **tricyclic antidepressants** used for treating depression (e.g. amitriptyline).
- **antipsychotics**, medicine to treat mental health problems.
- **cough and cold medicines and weight reducing medicines** (e.g. pseudoephedrine, amphetamine).
- **gold**, used to treat pain or arthritis.
- **antidiabetic medicines including insulin and vildagliptin**, used to lower blood sugar.
- **non-steroidal anti-inflammatory drugs** (NSAIDs), medicines to reduce inflammation and relieve pain (different types are listed below):
  - selective cyclooxygenase-2 inhibitors (COX-2 inhibitors, for example, ibuprofen);
  - acetylsalicylic acid (aspirin).

- **transplant rejection medicines**, used to prevent organ transplant rejection (e.g. ciclosporin, temsirolimus, sirolimus, everolimus).

If you are not sure if any of the above apply to you or your child, talk to the doctor or pharmacist before giving Aqumeldi.

#### **Aqumeldi with food, drink and alcohol**

You or your child should not drink alcohol while taking Aqumeldi. Alcohol may cause blood pressure to drop too much and you or your child may experience dizziness, light-headedness or faintness.

#### **Pregnancy, breast-feeding and fertility**

You must tell your doctor if you think you or your child are (or might become) pregnant. Your doctor will normally advise to stop taking Aqumeldi before becoming pregnant or as soon as knowing about the pregnancy and will advise to take another medicine instead of Aqumeldi.

Aqumeldi is not recommended in early pregnancy and must not be taken when more than 3 months pregnant, as it may cause serious harm to the baby if used after the third month of pregnancy (see section 2 “Do not give Aqumeldi if you or your child”).

If you are a female of childbearing potential, you must use effective contraception during and up to 1 week after treatment.

#### Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding and discuss whether to stop breast-feeding or stop taking Aqumeldi treatment.

#### **Driving and using machines**

Aqumeldi may make you or your child sleepy or affect concentration and co-ordination. This may affect performance at skilled tasks such as driving, riding a bicycle, or using machines.

#### **Aqumeldi contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially ‘sodium-free’.

### **3. How to use Aqumeldi**

Always use this medicine exactly as your or your child’s doctor or pharmacist has told you. Check with the doctor or pharmacist if you are not sure.

The dose will be advised by your or your child’s doctor and will depend on your or your child’s weight and how they respond to treatment.

- The recommended starting dose is up to 2 mg as a single dose.
- The recommended maintenance dose is 1 mg to 20 mg once a day.

Your child’s doctor will advise you when to increase the dose based on your child’s blood pressure, levels of potassium in the blood and kidney function.

### **INSTRUCTIONS FOR USE**

#### **Please read carefully before using the orodispersible tablet(s).**

Aqumeldi should only be taken by mouth. It is an orodispersible tablet, which means it dissolves in the mouth or in water. The tablet can be taken with or without meals.

1. Due to the small size of the tablets, use the scoop provided in the pack to collect the required number of orodispersible tablets from the bottle. As much as possible, avoid touching the tablets with your hands.
2. Place the orodispersible tablet(s) on the tongue, or into the space between the gum and the cheek (buccal cavity) and allow to disperse.
3. Do not crush the orodispersible tablets.

If the dose prescribed by the doctor is less than 0.25 mg, it can be achieved as follows:

1. Place one 0.25 mg orodispersible tablet to be dispersed in a 10 ml oral syringe.
2. Draw up 10 ml of fresh tap water into the syringe (up to the 10 ml graduation mark). Sterile water should be used in children under 6 months of age.
3. Carefully roll the syringe for 3 minutes until the orodispersible tablet is fully dispersed.
4. This results in a concentration of 0.025 mg/ml enalapril maleate.
5. 1 ml of the resulting solution will contain 0.025 mg enalapril, 4 ml will contain 0.1 mg enalapril.
6. The required volume of dispersion should then be administered immediately to the patient; do not store the dispersion in the oral syringe.

If you or your child is given the medicine through a feeding tube, the following procedure should be followed:

1. Remove the plunger from the syringe you use with the feeding tube (syringe not provided) and place the required number of orodispersible tablets in the barrel of the syringe.

Note: a maximum of four orodispersible tablets can be dispersed in 1 ml at any one time, the following procedure may need to be repeated to achieve the recommended dose.



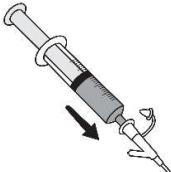
2. Replace the plunger and draw up 1 ml of fresh tap water. Sterile water should be used in children under 6 months of age.



3. Cap the syringe and carefully roll or mix for 3 minutes for the orodispersible tablets to disperse.



4. Remove the cap and give the dose via the feeding tube.



5. Flush the feeding tube with at least 3 ml of water after giving the medicine.

The solution should be given immediately to you or your child. Do not store.

Standard feeding tubes (polyurethane, polyvinylchloride and silicone) have been found to be suitable to use with this medicine.

**If you or your child takes more Aqumeldi than they should**

Do not give more medicine than your or your child's doctor tells you to. If you or your child has swallowed more tablets than the doctor has prescribed, contact your nearest hospital casualty department or doctor immediately. Take the medicine pack with you.

The most common signs and symptoms of overdose are fall in blood pressure (signs may include dizziness or light-headedness) and a state of almost complete lack of consciousness (stupor). Other symptoms may include forceful and rapid heartbeat, rapid pulse, anxiety, cough, kidney failure and rapid breathing.

**If you or your child forgets to take Aqumeldi**

If you or your child forgets to take Aqumeldi, skip the missed dose.

Take the next dose as usual.

Do not take a double dose to make up for a forgotten dose.

**If you or your child stops taking Aqumeldi**

Do not stop giving Aqumeldi unless your or your child's doctor tells you to.

If you have any further questions on the use of this medicine, ask your or your child's doctor, pharmacist or nurse.

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**The following serious side effects have been reported in adult patients. If you or your child develops any of these side effects, stop using the medicine and seek urgent medical advice:**

- Swelling of the lips, eyes, mouth or throat which may cause difficulty in breathing or swallowing (angioedema) common
- Blood disorders including changes in blood values such as lower number of white and red blood cells, lower haemoglobin, lower number of blood platelets – uncommon
- Heart attack (possibly due to very low blood pressure in certain high-risk patients, including those with blood flow problems of the heart or brain) - uncommon
- Stroke (possibly due to very low blood pressure in high-risk patients) – uncommon
- Blood disorders (bone marrow depression), including changes in blood values such as lower number of white blood cells (neutropenia), lower number of blood platelets (thrombocytopenia), lower levels of haemoglobin, lower levels of haematocrit, pancytopenia, agranulocytosis - rare
- Severe skin reactions with reddening and scaling of the skin, blistering or raw sores (Stevens-Johnson syndrome, Toxic epidermal necrolysis) – rare
- Sudden, unexpected rash or burning, red or peeling skin - rare
- Bone marrow stops producing new blood cells causing tiredness, lower ability to fight infection and uncontrolled bleeding (aplastic anaemia) - rare
- Inflammation of the liver, liver disease, increase in liver enzymes or bilirubin (measured in tests), jaundice (yellowing of the skin and/or eyes) - rare

## **Side effects seen in children taking Aqumeldi for heart failure:**

### ***Common (may affect up to 1 in 10 people)***

- Feeling dizzy, low blood pressure (dizziness postural)
- Cough,
- Sickness (vomiting)
- High levels of potassium (hyperkalaemia), as measured in the blood
- Slight increases of the protein albumin in the urine (microalbuminuria)

You or your child may feel dizzy when they start taking Aqumeldi. This is caused by a lowering of blood pressure. If this happens, it will help if they lie down. Please talk to your or your child's doctor.

## **Other possible side effects seen in adults taking enalapril include:**

### ***Very common (may affect more than 1 in 10 people)***

- Feeling dizzy
- Feeling weak (aesthesia)
- Feeling sick (nausea)
- Blurred vision
- Cough

### ***Common (may affect up to 1 in 10 people)***

- Diarrhoea
- Abdominal pain
- Vomiting
- Rash
- Headache
- Fainting (syncope)
- Low blood pressure
- Changes in heart rhythm
- Fast heartbeat
- Angina
- Chest pain
- Tiredness (Fatigue)
- Depression
- Increased potassium level (hyperkalaemia), as measured in blood tests
- Increased levels of creatinine (increased serum creatine), as measured in blood tests
- Abnormal loss of albumin in the urine (Microalbuminuria), as measured in urine tests
- Change in sense of taste
- Shortness of breath (dyspnoea)

### ***Uncommon (may affect up to 1 in 100 people)***

- Indigestion
- Constipation
- Loss of appetite (anorexia)
- Slow movement of food through the intestine
- Inflammation of the pancreas
- Irritated stomach (gastric irritation)
- Dry mouth
- Ulcer
- Impaired kidney function
- Kidney failure
- Runny nose
- Hoarseness
- Sore throat
- Fast or uneven heart beats (palpitations)
- Excessive breakdown of red blood cells causing tiredness and pale skin (haemolytic anaemia)

- Confusion,
- Difficulty sleeping
- Sleepiness
- Nervousness
- Feeling the skin prickling or being numb
- Spinning sensation (vertigo)
- Ringing in the ears (tinnitus)
- Asthma
- Asthma-associated tightness in chest (bronchospasm)
- Increased perspiration
- Itching
- Nettle rash
- Loss of hair
- Muscle cramps
- Flushing
- Low blood pressure when standing up (postural hypotension)
- Generally feeling unwell (malaise),
- Fever
- Erectile dysfunction (impotence)
- High level of proteins in the urine (measured in a test)
- Low level of blood sugar
- Low level of sodium (hyponatraemia), as measured in the blood
- High level of blood urea as measured in the blood

***Rare (may affect up to 1 in 1 000 people)***

- Small fluid-filled bumps on the skin (pemphigus)
- Liver failure (hepatic failure)
- Cholestasis (problems with the flow of bile)
- Increased liver enzymes
- Raynaud's phenomenon, where the hands and feet may become very cold and pale due to low blood flow
- Autoimmune diseases
- Strange dreams
- Sleep problems
- Accumulation of fluid or other substances in the lungs (as seen on X-rays)
- Inflammation of the nose
- Inflammation of the lungs caused by a build up of blood cells leading to difficulty in breathing (eosinophilic pneumonia)
- Inflammation of the mouth (stomatitis)
- Inflammation of the tongue (glossitis)
- Sores in the mouth (aphthous ulceration)
- Lower amount of urine produced
- Skin disorder due to an allergic reaction or infection (erythema multiforme)
- Enlarged breasts in men
- Swollen glands in neck, armpit or groin
- Swelling of the hands, feet or ankles

***Very rare (may affect up to 1 in 10 000 people)***

- Swelling in the intestine (intestinal angioedema)

***Not known (frequency cannot be estimated from the available data)***

- Overproduction of antidiuretic hormone, a hormone which helps the kidneys control the amount of water the body loses through the urine which causes fluid retention, resulting in weakness, tiredness or confusion (SIADH).
- Severe skin reactions. A symptom complex has been reported which may include some or all of the following: fever, inflammation of the blood vessels (serositis/vasculitis), muscle pain

(myalgia/myositis), joint pain (arthralgia/ arthritis). Rash, sensitivity to sunlight and UV-radiation or other skin manifestations may occur.

### **Reporting of side effects**

If you or your child gets any side effects, talk to your or your child's doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system (see below). By reporting side effects, you can help provide more information on the safety of this medicine.

Yellow Card Scheme

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

## **5. How to store Aqumeldi**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and bottle after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Aqumeldi contains**

- The active substance is enalapril maleate.
- The other excipients are: mannitol (E421), crospovidone, poly(vinyl acetate), povidone, sodium lauryl sulfate (see section 2 "Aqumeldi contains sodium"), sodium stearyl fumarate, colloidal anhydrous silica – (0.25 mg orodispersible tablet only), iron oxide yellow (E172) – (1 mg orodispersible tablet only).

### **What Aqumeldi looks like and contents of the pack**

Aqumeldi 0.25 mg orodispersible tablets are white, round, biconvex, 2 mm diameter tablets.

Aqumeldi 1 mg orodispersible tablets are yellowish to yellow, round, biconvex, 2 mm diameter tablets.

They both are supplied in a plastic bottle with a plastic child-resistant, tamper evident cap inside a cardboard carton. Each carton contains one bottle and one blue scoop.

Available packs of 0.25 mg or 1 mg containing 50, 100 or 200 orodispersible tablets per bottle. Not all pack sizes may be marketed.

The first time the bottle is opened, the seal needs to be broken:

- Hold the bottle firmly with one hand.
- With the other hand: push down firmly whilst twisting the cap anti-clockwise.
- Continue turning until the seal is broken.

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