

Package leaflet: Information for the patient

Qaialdo 10 mg/ml oral suspension spironolactone

Read all of this leaflet carefully before you start 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 doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Qaialdo is and what it is used for

Qaialdo contains the active substance spironolactone. Spironolactone belongs to a group of medicines called ‘diuretics’ (water tablets). Spironolactone works by blocking the effects of aldosterone, a hormone that helps control water balance in the body. Spironolactone causes you to excrete excess salt and water and keeps your potassium levels from getting too low. This reduces oedema. Spironolactone is used to treat various conditions in newborns, children and adults.

Qaialdo is used to treat refractory oedema (persistent swelling due to the build-up of fluid that has not responded to other treatment) associated with:

- congestive heart failure (when the heart does not pump blood as well as it should with build-up of fluid around the heart causing shortness of breath, tiredness and ankle swelling);
- hepatic cirrhosis (a type of liver disease) with ascites (a build-up of fluid in the abdomen) and oedema (swelling);
- malignant ascites (a condition in which fluid containing cancer cells collect in the abdomen);
- nephrotic syndrome (kidney disorder causing the kidneys to leak too much protein in the urine);
- essential hypertension (high blood pressure without a known cause).

Qaialdo is also used to diagnose and treat primary aldosteronism (a condition in which your body produces too much of a hormone called aldosterone, resulting in a build-up of fluid). Children should only be treated under guidance of a paediatric specialist.

2. What you need to know before you take Qaialdo

Do not take Qaialdo

- if you are allergic to spironolactone or any of the other ingredients of this medicine (listed in section 6).
- if you have Addison’s disease (a disorder in which the adrenal glands do not make enough of certain hormones).
- if you have hyperkalaemia (high blood potassium levels).

- if you have anuria (a condition in which a patient cannot make or pass urine).
- if you have sudden kidney failure.
- if you have severe kidney disease.
- if you are taking eplerenone (another medicine used to treat hyperaldosteronism).
- if you are taking potassium sparing diuretics (medicines that can increase urine production without the loss of potassium) or any potassium supplements.

Children with moderate to severe kidney disease must not take Qaialdo.

Warnings and precautions

Talk to your doctor or pharmacist before taking Qaialdo:

- if you suffer from kidney disease. This is especially important for children with hypertension
- if you suffer from liver disease.
- if you are an elderly patient and/or, have a blockage in the parts of the body that collect and pass out urine or suffer from a condition that can result in disturbance of electrolytes (salts such as sodium, potassium, calcium, chloride and bicarbonate in blood and other fluids in the body).
- if you have severe heart failure and are treated with Qaialdo your doctor will monitor potassium levels in your blood due to the risk of hyperkalaemia, which may be fatal. The recommended monitoring for potassium and creatinine is 1 week after initiation or increase in dose of spironolactone, then monthly for the first 3 months, then quarterly for a year, and then every 6 months.
- if you experience reduced kidney function or kidney failure you may have severe increases in the levels of potassium in your blood. This can affect the way your heart functions and in extreme cases this can be fatal.

Your doctor or nurse will perform regular blood tests to check levels of fluids and electrolytes (potassium and sodium).

Treatment with Qaialdo may increase levels of potassium and blood urea nitrogen (a marker for liver and kidney problems) and lower sodium levels, especially in the elderly and/or in patients with heart, kidney or liver problems. High potassium levels (hyperkalaemia) can be fatal in extreme cases.

Concomitant administration of Qaialdo with certain medicines, e.g. trimethoprim/sulfamethoxazole (co-trimoxazole), potassium supplements and food rich in potassium may lead to severe hyperkalaemia.

The symptoms of severe hyperkalaemia might include muscle cramps, irregular heart rhythm, diarrhoea, nausea, dizziness or headache.

Spironolactone may induce gynaecomastia (enlarged breasts), breast pain and menstrual irregularities (irregular periods).

Frequent blood tests are recommended, especially in the elderly and patients with impaired kidney function.

Other medicines and Qaialdo

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor, if you are using abiraterone for treatment of prostate cancer. Use with abiraterone is not recommended.

Tell your doctor, if you are using mitotane for treatment of malignant tumours of the adrenal glands. This medicine should not be used together with mitotane.

Concurrent use with carbenoxolone or lithium salts should be avoided.

Your doctor may wish to alter your dose of Qaialdo if you are taking any of the following:

- potassium sparing diuretics, and aldosterone blockers, angiotensin-converting enzyme (ACE) inhibitors, angiotensin II antagonists (risk of raised blood potassium levels)
- antipyrene used to reduce fever
- colestyramine, ammonium chloride (risk of raised blood potassium levels and acidosis)
- non-steroidal anti-inflammatory drugs (NSAIDs) such as acetylsalicylic acid, indometacin, ibuprofen or mefenamic acid (risk of raised blood potassium levels)
- potassium supplements (risk of raised blood potassium levels)
- noradrenaline
- regional or general anaesthesia
- heparin, low molecular weight heparin, medicines that prevent blood clots forming (risk of raised blood potassium levels)
- medicines known to cause hyperkalaemia (risk of raised blood potassium levels)
- trimethoprim and trimethoprim-sulfamethoxazole (risk of raised blood potassium levels)
- medicines for high blood pressure including other diuretics; digoxin or other cardiac glycosides used in the treatment of heart failure. Dose adjustment of these medicines may be required.

If you are going to have an operation where you will be given an anaesthetic, tell the doctor in charge that you are taking Qaialdo.

Qaialdo with food and drink

The use of Qaialdo with high potassium salt diet and salt substitutes containing potassium may lead to increased levels of potassium in your blood. See section 2. “Do not take Qaialdo”.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Qaialdo should not be used if you are breast-feeding. You should discuss the use of Qaialdo with your doctor, who will advise you to consider an alternative method of feeding your baby while you are taking this medicine.

Driving and using machines

Take care if you drive or operate machinery. Drowsiness and dizziness have been associated with spironolactone treatment and this may affect your ability to drive or operate machinery safely.

Qaialdo contains sodium benzoate (E211)

This medicine contains 0.75 mg sodium benzoate in each ml. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

Qaialdo contains sodium

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

Qaialdo contains sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

As Qaialdo 10 mg/ml contains 400 mg sucrose per ml, this has to be taken into consideration in terms of daily intake. This should be taken into account in patients with diabetes mellitus.

Qaialdo may be harmful to the teeth.

3. How to take Qaialdo

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

Dose

Your doctor will recommend the dose and frequency. The dose should be taken with food.

Use in adults

The doctor will decide what dose is right for your situation. Treatment will start at the lowest dose and may be increased if needed to a maximum of 400 mg spironolactone a day. If you are not sure how much to take, ask your doctor or pharmacist.

Use in the elderly

Your doctor will start you on a low starting dose and gradually increase the dose as needed to obtain the desired effect.

Use in children

If you are giving Qaialdo to a child, the dose you give will depend on the child's age and weight.

- The dose in a newborn child is 1 to 2 mg/kg per day in one or two divided doses.
- The dose in a child aged 1 month to 18 years is 1 to 3 mg/kg per day in one or two divided doses (but not exceeding 200 mg daily).
- Higher doses up to a maximum of 7 mg/kg per day in newborns and 9 mg/kg per day in older children (but not exceeding 400 mg daily) may be used in resistant ascites or primary aldosteronism.

Route and method of administration

Oral use.

This medicine should be taken with meals.

Always use the syringes provided to take your medicine.

The **smaller** syringe (1 ml) is used to take doses of less than or equal to 10 mg. It has clear markings at every 0.1 ml. Each 0.1 ml contains 1 mg of spironolactone. A full syringe will contain 10 mg of spironolactone. You should use only this syringe if the total dose you have to take is less than or equal to 10 mg.

The **larger** syringe (5 ml) is used to take doses of more than 10 mg. It has lines that indicate 0.2 ml increases and is marked at 1 ml intervals and at 2.5 ml. Each 1 ml contains 10 mg of spironolactone. A full syringe will contain 50 mg of spironolactone.

For doses more than 10 mg (1 ml) that need to be measured in 0.1 ml step ups (for example 1.5 ml), you should use both syringes:

1. Use the larger 5 ml syringe to measure up to the nearest 0.2 ml line (for example, 1.4 ml).
2. Then use the smaller 1 ml syringe to measure the remaining dose (for example, 0.1 ml).
3. Take each dose one after the other.

It is important to use the correct dosing syringe for your medicine. Your doctor or pharmacist will tell you which syringe to use depending on the dose prescribed for you.

Dose (mg)	Volume of Qaialdo to draw up (ml)	Which syringe to use?
5	0.5	Small 1 ml
10	1.0	Small 1 ml
15	1.5	Both syringes: 1.4 ml (Large 5 ml) 0.1 ml (Small 1 ml)
20	2.0	Large 5 ml
21	2.1	Both syringes: 2.0 ml (Large 5 ml) 0.1 ml (Small 1 ml)
25	2.5	Large 5 ml
50	5.0	Large 5 ml
100	10.0	Large 5 ml
200	20.0	Large 5 ml

If you are taking or giving the medicine to a child or somebody else, wash your hands before and after.

When you use the medicine follow the instructions below:



Figure 1

Figure 2

Figure 3

Figure 4

Figure 5

1. **Shake the bottle thoroughly** before use (to ensure the medicine is well mixed) (**figure 1**).
2. Remove the bottle cap (**figure 2**) and push the adaptor firmly into the top of the bottle and leave in place for future doses (**figure 3**).
3. Push the tip of the dosing syringe into the hole in the adaptor (**figure 4**). **Your doctor or pharmacist will advise you of the correct syringe to use, either the 1-ml or the 5-ml syringe in order to give the correct dose.**
4. Turn the bottle upside down (**figure 5**).
5. Pull the plunger of the syringe back so that the medicine is drawn from the bottle into the syringe. Pull the plunger back to the point on the scale that corresponds to the dose prescribed (**figure 5**). If you are not sure about how much medicine to draw into the syringe, always ask your doctor or nurse for advice.
6. Turn the bottle back the right way up and carefully remove the syringe from the adaptor, holding it by the barrel rather than the plunger.
7. Gently put the tip of the syringe into your mouth and to the inside of your cheek.
8. Slowly and gently push the plunger down to gently squirt the medicine into the inside of your cheek and swallow it. **DO NOT** forcefully push down the plunger, or squirt the medicine to the back of your mouth or throat, as you may choke.
9. Remove the syringe from your mouth.
10. Swallow the dose of oral suspension then drink some water, making sure no medicine is left in your mouth.
11. Put the cap back on the bottle with the adaptor left in place. Ensure that the cap is tightly closed.
12. Wash the syringe with warm water and rinse well. Hold the syringe under water and move the plunger up and down several times to make sure the inside of the syringe is clean. Let the syringe air dry completely before you use that syringe again for dosing. Do not wipe dry. Store the syringe in a hygienic place with the medicine.

Repeat the above for each dose as instructed by your doctor or pharmacist.

If you take more Qaialdo than you should

If you accidentally take more Qaialdo than you should, contact your doctor or nearest hospital accident and emergency department immediately.

The symptoms of an overdose are feeling drowsy, dizzy, feeling dehydrated and you may feel confused. Do not drive.

You may also feel or be sick, suffer from diarrhoea and may have skin rashes that will appear as flat red areas of skin with overlapping small raised bumps.

Changes in your blood sodium and potassium levels may leave you feeling weak and suffering from tingling, prickling or numbness of the skin and/or muscle spasms but these symptoms are unlikely to be associated with severe overdose.

If you forget to take Qaialdo

Do not take a double dose to make up for a forgotten dose. If you forget to take your dose, take it as soon as you remember, unless it is within 8 hours of the next dose.

If you stop taking Qaialdo

It is important to keep taking Qaialdo until your doctor tells you to stop, even if you start to feel better.

If you stop taking Qaialdo too soon, your condition may get worse.

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

4. Possible side effects

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

Tell your doctor immediately if you experience any of the following symptoms after taking this medicine. Although they are very rare, the symptoms can be severe.

- Itchiness and blistering of the skin around the lips and the rest of the body, red or purple rash spreading and forming blisters (Stevens-Johnson syndrome)
- Detachment of the top layer of skin from the lower layers of skin, all over the body (toxic epidermal necrolysis - TEN)
- Skin rash, fever and swelling (which could be symptoms of something more serious, Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS))
- Yellow skin and eyes (spironolactone can cause impairment of liver function)
- Irregular heartbeat that can be fatal, tingling sensation, paralysis (loss of muscle function) or difficulty in breathing; which may be symptoms of raised potassium levels in your blood. Your doctor will conduct regular blood tests to monitor potassium and other electrolyte levels. He or she may stop your treatment if necessary.

List of other side effects of Qaialdo by frequency:

Very common: may affect more than 1 in 10 people

- Hyperkalaemia (high blood potassium levels)

Common: may affect up to 1 in 10 people

- Confusion
- Dizziness
- Nausea (Feeling sick)

- Pruritus (Itching)
- Rash
- Muscle or leg spasms
- Sudden kidney failure
- Gynaecomastia (Breast enlargement in men)
- Breast pain (in men)
- Malaise (Feeling generally unwell)

Uncommon: may affect up to 1 in 100 people

- Changes in the breast such as breast lumps (in men)
- Disturbances in body electrolytes such as high blood calcium
- Abnormal functioning of the liver
- Urticaria (itchy rash)
- Menstrual problems in women
- Breast pain (in women)

Not known: frequency cannot be estimated from the available data

- Leucopenia (low levels of white blood cells)
- Agranulocytosis (very low level of a type of white blood cell called granulocytes, which are important for fighting off infection)
- Anaemia (low levels of red blood cells which can cause tiredness and pale skin)
- Thrombocytopenia (low levels of blood platelets which can lead to bleeding and bruising)
- Eosinophilia (an excess of eosinophils, a type of white blood cell)
- Purpura (purple patches like bruising)
- Change in sex drive for both men and women
- Impotence in men
- Stomach and gut problems
- Pemphigoid (skin condition presenting with fluid-filled blisters)
- Drug rash with eosinophilia and systemic symptoms (a severe reaction affecting the skin, blood and internal organs)
- Stevens-Johnson syndrome (life-threatening reaction with flu-like symptoms and painful rash affecting the skin, mouth, eyes and genitals)
- Toxic epidermal necrolysis (life-threatening reaction with flu-like effects and blistering in the skin, mouth eyes and genitals)
- Alopecia (hair loss)
- Hypertrichosis (excessive hair growth)
- Headache
- Drowsiness
- Ataxia (inability to co-ordinate muscle movements)
- Fever

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Qaialdo

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 after EXP. The expiry date refers to the last day of that month.

After first opening of the bottle, store below 25°C and discard any unused contents after 12 weeks.
Keep the bottle tightly closed.

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 Qaialdo contains

- The active substance is spironolactone. Each ml of suspension contains 10 mg spironolactone.
- The other ingredients are sodium benzoate (E 211), sucrose, sodium citrate (E 331), citric acid monohydrate (E 330), strawberry flavour liquid, masking flavour, polysorbate 80 (E 433), simeticone emulsion 30%, xanthan gum (E 415) and purified water.

See section 2 “Qaialdo contains sodium benzoate”, “Qaialdo contains sodium” and “Qaialdo contains sucrose”.

What Qaialdo looks like and contents of the pack

Qaialdo is a white to off white viscous oral suspension.

It comes in glass bottles of 150 ml capped with a child-resistant closure.

Each pack contains one bottle, a bottle adaptor and two dosing syringes (a syringe graduated to 1 ml and a syringe graduated to 5 ml).

Your doctor or pharmacist will advise which syringe to use depending on the dose that has been prescribed.

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