ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Qaialdo 10 mg/ml oral suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of suspension contains 10 mg spironolactone.
Each bottle of 150 ml contains 1 500 mg of spironolactone.

Excipients with known effect

This medicine contains 0.75 mg sodium benzoate and 400 mg sucrose in each ml.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension
White to off white viscous oral suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

In the management of refractory oedema associated with congestive cardiac failure; hepatic cirrhosis with ascites and oedema, malignant ascites, nephrotic syndrome, diagnosis and treatment of primary aldosteronism, essential hypertension.

Neonates, children and adolescents should only be treated under guidance of a paediatric specialist. There is limited paediatric data available (see sections 5.1 and 5.2).

4.2 Posology and method of administration

Posology

Adults

Congestive heart failure with oedema
Usual dose - 100 mg/day. In difficult or severe cases the dose may be gradually increased up to 200 mg/day. When oedema is controlled, the usual maintenance level is 75 mg/day to 200 mg/day.

Severe heart failure in conjunction with standard therapy (New York Heart Association Class III-IV)
Based on the randomized aldactone evaluation study (RALES), treatment in conjunction with standard therapy should be initiated at a dose of spironolactone 25 mg once daily in patients with a serum potassium ≤ 5.0 mEq/L and serum creatinine ≤ 2.5 mg/dL. Patients who tolerate 25 mg once daily may have their dose increased to 50 mg once daily as clinically indicated. Patients who do not tolerate 25 mg once daily may have their dose reduced to 25 mg every other day. See section 4.4 for advice on monitoring serum potassium and serum creatinine.

Hepatic cirrhosis with ascites and oedema
If urinary Na^+/K^+ ratio is greater than 1.0, 100 mg per day. If the ratio is less than 1.0, 200 mg/day to 400 mg/day. Maintenance dose should be individually determined.

Malignant ascites

Initial dose usually 100 mg/day to 200 mg/day. In severe cases the dose may be gradually increased up to 400 mg/day. When oedema is controlled, maintenance dose should be individually determined.

Nephrotic syndrome
Usual dose – 100 mg/day to 200 mg/day. Spironolactone has not been shown to be anti-inflammatory, nor to affect the basic pathological process. Its use is only advised if glucocorticoids by themselves are insufficiently effective.

Diagnosis and treatment of primary aldosteronism
Spironolactone may be employed as an initial diagnostic measure to provide presumptive evidence of primary hyperaldosteronism while patients are on normal diets.

- Long test: Spironolactone is administered at a daily dose of 400 mg for 3 to 4 weeks. Correction of hypokalaemia and of hypertension provides presumptive evidence for the diagnosis of primary hyperaldosteronism.

- Short test: Spironolactone is administered at a daily dose of 400 mg for 4 days. If serum potassium increases during spironolactone administration but drops when spironolactone is discontinued, a presumptive diagnosis of primary hyperaldosteronism should be considered.

After the diagnosis of hyperaldosteronism has been established by more definitive testing procedures, spironolactone may be administered in doses of 100 mg to 400 mg daily in preparation for surgery. For patients who are considered unsuitable for surgery, Spironolactone may be employed for long term maintenance therapy at the lowest effective dose determined for the individual patient.

Essential hypertension
Usual dose – 50 mg/day to 100 mg/day, which for difficult or severe cases may be gradually increased at 2 weekly intervals up to 200 mg/day. Treatment should be continued for 2 weeks or longer since an adequate response may not occur before this time. Dose should subsequently be adjusted according to the response of the patient.

Special populations

Elderly
It is recommended that treatment is started with the lowest dose and titrated upwards as required to achieve maximum benefit. Care should be taken in severe hepatic and renal impairment which may alter spironolactone metabolism and excretion.

Renal/ hepatic impairment
Patients with mild renal impairment (glomerular filtration rate (GFR) 60 – 90 ml/min) should be started on the lowest dose. Serum potassium levels and renal function should be monitored closely. Spironolactone is contraindicated in patients with moderate (GFR 30 - < 60 ml/min) to severe (GFR < 30ml/min) renal impairment (see sections 4.3 and 4.4).

Since impaired hepatic function may result in reduced elimination of spironolactone and its metabolites, patients with impaired hepatic function should be started on the lowest dose and titrated slowly. Patients should be monitored for dose related adverse reactions (see section 4.4).

Paediatric population
Initiate treatment with the smallest dose and adjust on the basis of response and tolerance (see sections 4.3 and 4.4).
Diuresis in congestive heart failure, ascites, oedema and nephrotic syndrome;
- Neonate: 1-2 mg/kg/daily in 1-2 divided doses.
- Infant or child 1 month to 18 years: 1-3 mg/kg daily in 1-2 divided doses (maximum 200 mg daily).

Primary hyperaldosteronism; resistant ascites.

- Neonate: up to a maximum of 7 mg/kg daily may be used.
- Infant or Child 1 month to 18 years: up to a maximum of 9 mg/kg daily (total maximum 400 mg daily) may be used.

Neonates, children and adolescents should only be treated under guidance of a paediatric specialist. There is limited paediatric data available (see sections 5.1 and 5.2).

The paediatric table below shows, for a range of ages, weight and doses, the dose (mg) to volume (ml) conversion using the two oral syringes.

Table 1: Dose (mg) to volume (ml) conversion using oral syringe. **Daily doses are displayed.**

Age (Years)	**Weight* (Kg)**	**Dose†**					
		1 mg/kg		**2 mg/kg**		**3 mg/kg**	
		mg	**ml**	**mg**	**ml**	**mg**	**ml**
0	3.3	3.3	0.3	6.6	0.7	9.9	1.0
1 month	4.5	4.5	0.5	9.0	0.9	13.5	1.4
2 month	5.6	5.6	0.6	11.2	1.1	16.8	1.7
3 month	6.4	6.4	0.6	12.8	1.3	19.2	1.9
4 month	7.0	7.0	0.7	14.0	1.4	21.0	2.1
5 month	7.5	7.5	0.8	15.0	1.5	22.5	2.3
6 month	7.9	7.9	0.8	15.8	1.6	23.7	2.4
1.0	9.6	9.6	1.0	19.2	1.9	28.8	2.9
1.5	10.9	10.9	1.1	21.8	2.2	32.7	3.3
2.0	12.2	12.2	1.2	24.4	2.4	36.6	3.7
3.0	14.3	14.3	1.4	28.6	2.9	42.9	4.3
4.0	16.3	16.3	1.6	32.6	3.3	48.9	4.9
5.0	18.3	18.3	1.8	36.6	3.7	54.9	5.5
6.0	20.5	20.5	2.1	41.0	4.1	61.5	6.2
7.0	22.9	22.9	2.3	45.8	4.6	68.7	6.9
8.0	25.4	25.4	2.5	50.8	5.1	76.2	7.6
9.0	28.1	28.1	2.8	56.2	5.6	84.3	8.4

*50th percentile for boys extracted from WHO (0-10 years) growth charts
†Doses less than or equal to 10 mg to be drawn up using the 1 ml oral syringe. Doses greater than 10 mg to be drawn up using the 5 ml oral syringe or a combination of both syringes (shaded cells). Both syringes have graduations at every 0.1 ml (1 mg).

Method of administration

Spironolactone should be taken together with a meal.

This medicinal product is for oral use. The bottle should be shaken thoroughly before use for redispersing the suspension.

Two dosing syringes (a 1 ml syringe with black font and a 5 ml syringe with red font, both graduated in 0.1 ml increments, allowing accurate and reproducible dosing in 1 mg increments) are provided for accurate measurement of the prescribed dose of the oral suspension. The healthcare professional should advise the patient or carer which syringe to use to ensure that the correct volume is administered.

The healthcare professional should advise the patient or carer to place the tip of the syringe into the mouth and to the inside of the cheek, and the contents gently released. To assist accurate and consistent dose delivery to the stomach, water should be taken after each dose of spironolactone.
In adults without swallowing difficulties, solid oral formulations may be more appropriate and convenient.

4.3 Contraindications

Spironolactone is contraindicated in adult and paediatric patients with the following:

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Acute renal insufficiency, significant renal compromise (GFR < 30 ml/min), anuria
- Addison's disease
- Hyperkalaemia (> 5.5 mEq/L)
- Concomitant use of eplerenone
- In paediatric patients with moderate to severe renal impairment.

Spironolactone should not be administered concurrently with other potassium-conserving diuretics and potassium supplements should not be given routinely with spironolactone as hyperkalaemia may be induced.

4.4 Special warnings and precautions for use

Monitoring fluid and electrolyte state

Patients who are being treated with this preparation require regular supervision with monitoring of fluid and electrolyte state. Periodic estimation of serum electrolytes is recommended due to the possibility of hyperkalaemia, hyponatremia and possible transient blood urea nitrogen (BUN) elevation, especially in the elderly and/or in patients with pre-existing impaired renal or hepatic function.
The preparation should only be used with particular caution in elderly patients or those with potential obstruction of the urinary tract, or with disorders rendering their electrolyte balance precarious.

Concomitant use of spironolactone with other potassium sparing diuretics, angiotensin- converting enzyme (ACE) inhibitors, nonsteroidal anti-inflammatory medicinal products, angiotensin II antagonists, aldosterone blockers, heparin, low molecular weight heparin or other medicinal products or conditions known to cause hyperkalaemia, potassium supplements, a diet rich in potassium, or salt substitutes containing potassium, may lead to severe hyperkalaemia (see section 4.5).

Hyperkalaemia may also occur in patients with impaired renal function. Cardiac dysrhythmias, occasionally fatal, may result.

Reversible hyperchloraemic metabolic acidosis, usually in association with hyperkalaemia, has been reported to occur in some patients with decompensated hepatic cirrhosis, even when renal function is normal.

Dilution hyponatraemia may occur in combination with other diuretics (see section 4.5).

Hyperkalaemia in patients with severe heart failure

Hyperkalaemia may be fatal. It is critical to monitor and manage serum potassium in patients with severe heart failure receiving spironolactone. Avoid using other potassium-sparing diuretics. Avoid using oral potassium supplements in patients with serum potassium > 3.5 mEq/L. The recommended monitoring for potassium and creatinine is 1 week after initiation or increase in dose of spironolactone, monthly for the first 3 months, then quarterly for a year, and then every 6 months. Discontinue or interrupt treatment for serum potassium > 5 mEq/L or for serum creatinine > 4 mg/dL (see section 4.2).

Concomitant use with cardiac glycosides or hypotensive agents

The concomitant administration of this preparation with cardiac glycosides or hypotensive agents may necessitate adjustment of those medicinal products (see section 4.5).

Urea

Reversible increases in blood urea may occur during use of spironolactone especially in the presence of impaired renal function.

Paediatric population

Potassium-sparing diuretics should be used with caution in hypertensive paediatric patients with mild renal insufficiency because of the risk of hyperkalaemia. Spironolactone is contraindicated for use in paediatric patients with moderate or severe renal impairment (see section 4.3).

Excipients with known effect

Sodium benzoate

This medicinal product contains 0.75 mg sodium benzoate in each 1 ml which is equivalent to 112.5 mg/150 ml. Increase in bilirubinaemia following its displacement from albumin may increase neonatal jaundice which may develop into kernicterus (non-conjugated bilirubin deposits in the brain tissue).

Sodium

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

Sucrose

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. As this medicinal product 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 10 mg/ml may be harmful to the teeth.

4.5 Interaction with other medicinal products and other forms of interaction

Interactions affecting the use of this medicinal product

Interactions affecting the potassium homeostasis

Concomitant use of medicinal products known to cause hyperkalaemia (such as lisinopril, valsartan, indomethacin) with spironolactone may result in severe hyperkalaemia.
In addition, concomitant use of trimethoprim/sulfamethoxazole (co-trimoxazole) with spironolactone may result in clinically relevant hyperkalaemia.

Since ACE inhibitors decrease aldosterone production, they should not routinely be used with spironolactone, particularly in patients with marked renal impairment.

Hyperkalaemic metabolic acidosis has been reported in patients given spironolactone concurrently with ammonium chloride or colestyramine.

Interactions attenuating the natriuretic effect of spironolactone

Non-steroidal anti-inflammatory medicinal products such as acetylsalicylic acid, indomethacin and mefenamic acid may attenuate the natriuretic efficacy of diuretics due to the inhibition of intra-renal synthesis of prostaglandins and have been shown to attenuate the diuretic effect of spironolactone.

Interactions affecting the use of other medicinal products

Concurrent use with carbenoxolone or lithium salts should be avoided.

Spironolactone binds to the androgen receptor and may increase prostate specific antigen (PSA) levels in abiraterone-treated prostate cancer patients. Use with abiraterone is not recommended.

Potentiation of the effect of other diuretics and antihypertensive medicinal products occurs and their dose may need to be reduced by about 50% when spironolactone is added to the treatment regime, and then adjusted as necessary. Concomitant administration with cardiac glycosides may necessitate adjustment of the doses of these medicinal products.

Spironolactone has been shown to increase the half-life of digoxin. Spironolactone has been reported to increase serum digoxin concentration and to interfere with certain serum digoxin assays. In patients receiving digoxin and spironolactone the digoxin response should be monitored by means other than serum digoxin concentrations, unless the digoxin assay used has been proven not to be affected by spironolactone therapy. If it proves necessary to adjust the dose of digoxin, patients should be carefully monitored for evidence of enhanced or reduced digoxin effect.

Spironolactone reduces vascular responsiveness to noradrenaline.

Caution should be exercised in the management of patients subjected to regional or general anaesthesia while they are being treated with spironolactone.

Spironolactone enhances the metabolism of antipyrine.

In fluorimetric assays, spironolactone may interfere with the estimation of compounds with similar fluorescence characteristics.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no studies of spironolactone in pregnant women. Studies in animals have shown reproductive toxicity (see section 5.3). Qaialdo is not recommended during pregnancy and in women of childbearing potential not using contraception.

Breast-feeding

Canrenone is excreted in human milk. Qaialdo should not be used during breast-feeding.

Fertility

Studies in animals suggest spironolactone may impair fertility (see section 5.3).

4.7 Effects on ability to drive and use machines

Somnolence and dizziness have been reported to occur in some patients. Caution is advised when driving or operating machinery until the response to initial treatment has been determined.

4.8 Undesirable effects

Summary of the safety profile

The most frequent adverse reactions of spironolactone include: hyperkalaemia, reported in 17.5% of patients, particularly in patients with renal impairment or if receiving ACE-inhibitors or angiotensin II antagonists concomitantly; gynaecomastia and breast pain, reported in 9% of males.

The following undesirable effects have been observed in clinical trials and reported during treatment with spironolactone with the following frequencies: very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1 000 to < 1/100); rare (≥ 1/10 000 to < 1/1 000); very rare (< 1/10 000); not

known (cannot be estimated from the available data). Table 2 presented below is according to the MedDRA system organ classification and frequency. Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

Table 2 Tabulated list of adverse reactions

System organ class	**Frequency**	**Adverse reactions**
Neoplasms benign, malignant and unspecified (including cysts and polyps)	Uncommon	Benign breast neoplasm (male)
Blood and lymphatic system disorders	Not known	Leukopenia, Agranulocytosis, Thrombocytopenia, Anaemia, Eosinophilia Purpura
Metabolism and nutrition disorders	Very common	Hyperkalaemia***
	Uncommon	Electrolyte imbalance
Psychiatric disorders	Common	Confusional state
	Not known	Libido disorder
Nervous system disorders	Common	Dizziness
	Not known	Ataxia, Headache, Drowsiness, Lethargy
Gastrointestinal disorders	Common	Nausea
	Not known	Gastrointestinal disorder
Hepatobiliary disorders	Uncommon	Hepatic function abnormal
Skin and subcutaneous tissue disorders	Common	Pruritus, Rash
	Uncommon	Urticaria
	Not known	Toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome, Drug reaction with eosinophilia and systemic symptoms (DRESS), Pemphigoid, Alopecia, Hypertrichosis
Musculoskeletal and connective tissue disorders	Common	Muscle spasms
Renal and urinary disorders	Common	Acute kidney injury
Reproductive system and breast disorders	Common	Gynaecomastia*, Breast pain**
	Uncommon	Menstrual disorder
	Not known	Impotence
General	Common	Malaise

disorders and administration site conditions	Not known	Drug fever

* Gynaecomastia may develop in association with the use of spironolactone. Development appears to be related to both dose level and duration of therapy and is normally reversible when the medicinal product is discontinued. In rare instances some breast enlargement may persist.

** In clinical trials, breast pain was reported more commonly in males than in females.

*** Arrhythmia, chest pain, nausea, diarrhoea, paraesthesia, weakness, flaccid paralysis or muscle spasm and may be difficult to distinguish clinically from hypokalaemia. Electrocardiographic changes are the earliest specific signs of potassium disturbance.

Paediatric population

Frequency, type and severity of adverse reactions in children are expected to be similar to adults.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

4.9 Overdose

Symptoms

Acute overdose may be manifested by drowsiness, mental confusion, nausea, vomiting, dizziness, diarrhoea or maculopapular or erythematous rash. Dehydration may occur. Hyponatraemia or hyperkalaemia may be induced but these effects are unlikely to be associated with acute overdose. See section 4.8 for the symptoms of hyperkalaemia.

Treatment

No specific antidote has been identified. Spironolactone use should be discontinued. Improvement may be expected after withdrawal of the medicinal product. General supportive measures including replacement of fluids and electrolytes may be indicated. For hyperkalaemia, reduce potassium intake, administer potassium-excreting diuretics, intravenous glucose with regular insulin, or oral ion-exchange resins.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: diuretics, aldosterone antagonists and other potassium-sparing agents, ATC code C03DA01

Mechanism of action

Spironolactone, as a competitive aldosterone antagonist, increases sodium excretion whilst reducing potassium loss at the distal renal tubule. It has a gradual and prolonged action, maximum response being usually attained after 2 to 3 days treatment. Combination of spironolactone with a conventional, more proximally acting diuretic usually enhances diuresis without excessive potassium loss.

Clinical efficacy and safety

Severe heart failure

RALES was a multinational, double-blind study in 1 663 patients with an ejection fraction of ≤ 35%, a history of New York Heart Association (NYHA) Class IV heart failure within 6 months, and Class III-IV heart failure at the time of randomization. All patients were required to be taking a loop diuretic and, if tolerated, an ACE inhibitor. Patients with a baseline serum creatinine of > 2.5 mg/dL or a recent increase of 25% or with a baseline serum potassium of > 5.0 mEq/L were excluded. Patients were randomized 1:1 to spironolactone 25 mg orally once daily or matching placebo. Patients who tolerated 25 mg once daily had their dose increased to 50 mg once daily as clinically indicated. Patients who did not tolerate 25 mg once daily had their dose reduced to 25 mg every other day. The primary endpoint for RALES was time to all-cause mortality. RALES was terminated early, after a mean follow-up of 24 months, because of significant mortality benefit detected on a planned interim analysis. Spironolactone reduced the risk of death by 30% compared to placebo (p< 0.001-95% confidence interval 18% - 40%). Spironolactone reduced the risk of cardiac death, primarily sudden death and death from progressive heart failure by 31% compared to placebo (p< 0.001-95% confidence interval 18% - 42%).

Spironolactone also reduced the risk of hospitalization for cardiac causes (defined as worsening heart failure, angina, ventricular arrhythmias or myocardial infarction) by 30% (p < 0.001-95% confidence interval 18% - 41%). Changes in NYHA class were more favourable with spironolactone: In the spironolactone group, NYHA class at the end of the study improved in 41% of patients and worsened in 38% compared to improved in 33% and worsened in 48% in the placebo group (p < 0.001).

Paediatric population

There is a lack of substantive information from clinical studies on spironolactone in children. This is a result of several factors: the few trials that have been performed in the paediatric population, the use of spironolactone in combination with other agents, the small numbers of patients evaluated in each trial and the different indications studied. The dose recommendations for paediatrics are based upon clinical experience and case studies documented in the scientific literature.

5.2 Pharmacokinetic properties

Spironolactone is well absorbed orally and is principally metabolised to active metabolites: sulfur containing metabolites (80%) and partly canrenone (20%). Although the plasma half- life of spironolactone itself is short (1.3 hours) the half-lives of active metabolites are longer (ranging from 2.8 to 11.2 hours).

Paediatric population

There are no pharmacokinetic data available in respect of use in paediatric population. The dose recommendations for paediatrics are based upon clinical experience and case studies documented in the scientific literature.

5.3 Preclinical safety data

Carcinogenicity

Orally administered spironolactone has been shown to be a tumorigen in dietary administration studies performed in rats, with its proliferative effects manifested on endocrine organs and the liver. In an 18-month study using doses of about 50, 150 and 500 mg/kg/day (about 1x, 4x, and 12x, respectively, the maximum human recommended daily dose of 400 mg/day based on body surface area), there were statistically significant increases in benign adenomas of the thyroid and testes and, in male rats, a dose-related increase in proliferative changes in the liver (including hepatocytomegaly and hyperplastic nodules). In 24-month studies in which rats were administered doses of about 10, 30, 100, and 150 mg/kg/day of spironolactone (about 0.2x, 0.7x, and 2x, respectively, the maximum recommended daily dose of 400 mg/day based on body surface area), the range of proliferative effects

included significant increases in hepatocellular adenomas and testicular interstitial cell tumours in males, and significant increases in thyroid follicular cell adenomas and carcinomas in both sexes. There was also a statistically significant increase in benign uterine endometrial stromal polyps in females.
A dose related (above 30 mg/kg/day) incidence of myelocytic leukaemia was observed in rats fed daily doses of potassium canrenoate (a compound chemically similar to spironolactone and whose primary metabolite, canrenone, is also a major product of spironolactone in man) for a period of 1 year. In 2-year studies in the rats, oral administration of potassium canrenoate was associated with myelocytic leukaemia and hepatic, thyroid, testicular and mammary tumours.

Genotoxicity

Neither spironolactone nor potassium canrenoate produced mutagenic effects in tests using bacteria or yeast. In the absence of metabolic activation, neither spironolactone nor potassium canrenoate has been shown to be mutagenic in mammalian tests in vitro. In the presence of metabolic activation, spironolactone has been reported to be negative in some mammalian mutagenicity tests in vitro and positive for mutagenicity in other mammalian tests in vitro. In the presence of metabolic activation, potassium canrenoate has been reported to test positive for mutagenicity in some mammalian tests in vitro, inconclusive in others, and negative in still others.

Fertility and reproductive toxicity

In a three-litter reproduction study in which female rats received dietary doses of 15 and 50 mg/kg/day of spironolactone (about 0.4x and 1x, respectively, the maximum human recommended daily dose of 400 mg/day based on body surface area), there were no effects on mating and fertility, but there was a small increase in incidence of stillborn pups at 50 mg/kg/day.
Spironolactone was devoid of teratogenic effects in mice. Rabbits receiving spironolactone showed reduced conception rate, increased resorption rate, and lower numbers of live births. No embryotoxic effects were seen in rats administered high doses, but limited, dose-related hyprolactinemia and decreased ventral prostate and seminal vesicle weights in males, and increasing luteinizing hormone secretion and ovarian and uterine weights in females were reported. Feminization of the external genitalia of male fetuses was reported in another study in rats. When injected into female rats (100 mg/kg/day for 7 days, i.p.) (about 2x the maximum human recommended daily dose of 400 mg/day based on body surface area), spironolactone was found to increase the length of the estrous cycle by prolonging diestrus during treatment and inducing constant diestrus during a 2-week post-treatment observation period. These effects were associated with retarded ovarian follicle development and a reduction in circulating estrogen levels, which would be expected to impair mating, fertility and fecundity. Spironolactone (100 mg/kg/day) (about 1x, the maximum human recommended daily dose of 400 mg/day based on body surface area), administered i.p. to female mice during a 2-week cohabitation period with untreated males, decreased the number of mated mice that conceived (effect shown to be caused by an inhibition of ovulation) and decreased the number of implanted embryos in those that became pregnant (effect shown to be caused by an inhibition of implantation), and at 200 mg/kg (about 2x, the maximum human recommended daily dose of 400 mg/day based on body surface area) also increased the latency period to mating.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened bottle: 2 years
After first opening: Keep the bottle tightly closed and store below 25°C. Discard any unused contents after 12 weeks.

6.4 Special precautions for storage

Before first opening, this medicinal product does not require any special storage conditions.

For storage conditions after first opening, see section 6.3.

6.5 Nature and contents of container

Amber type III glass bottle with tamper evident child-resistant closure (high density polyethylene-HDPE with expanded polyethylene liner) containing 150 ml of oral suspension.

Each pack contains one bottle, a low density polyethylene (LDPE) bottle adaptor and 2 dosing syringes (a 1 ml syringe graduated in 0.1 ml increments and a 5 ml syringe graduated in 0.1 ml increments).

6.6 Special precautions for disposal and other handling

The bottle should be shaken thoroughly before use to ensure the oral suspension is well mixed.

Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Nova Laboratories Ireland Limited
3rd Floor, Ulysses House
Foley Street, Dublin 1
D01 W2T2
Ireland

8. MARKETING AUTHORISATION NUMBER(S)

EU/1/23/1731/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:

10. DATE OF REVISION OF THE TEXT

Detailed information on this medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu

ANNEX II

A. MANUFACTURER(S) RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

A. MANUFACTURER(S) RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer(s) responsible for batch release

Pronav Clinical Ltd.
Unit 5
Dublin Road Business Park
Carraroe, Sligo
F91 D439
Ireland

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Medicinal product subject to medical prescription (See Annex I: Summary of Product Characteristics, section 4.2).

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

- **Periodic safety update reports (PSURs)**

The requirements for submission of PSURs for this medicinal product are set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and any subsequent updates published on the European medicines web-portal.

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

- **Risk management plan (RMP)**

The marketing authorisation holder (MAH) shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the marketing authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:

- At the request of the European Medicines Agency;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON

1. NAME OF THE MEDICINAL PRODUCT

Qaialdo 10 mg/ml oral suspension
spironolactone

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each ml of suspension contains 10 mg spironolactone.

3. LIST OF EXCIPIENTS

Also contains sodium benzoate and sucrose. See package leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Oral suspension
150 ml
Bottle
Bottle adaptor
1 ml and 5 ml dosing syringes

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.
Take as directed by your doctor using the dosing syringes provided.
Shake the bottle well before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP
Discard 12 weeks after first opening.
Open date: _____

9. SPECIAL STORAGE CONDITIONS

After first opening, keep the bottle tightly closed and store below 25°C.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Nova Laboratories Ireland Limited
3rd Floor
Ulysses House
Foley Street, Dublin 1
D01 W2T2
Ireland

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/23/1731/001

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Qaialdo

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC
SN
NN

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

BOTTLE LABEL

1. NAME OF THE MEDICINAL PRODUCT

Qaialdo 10 mg/ml oral suspension
spironolactone

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each ml of suspension contains 10 mg spironolactone.

3. LIST OF EXCIPIENTS

Also contains sodium benzoate and sucrose. See package leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Oral suspension
150 ml

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.
Take as directed by your doctor using the dosing syringes provided.
Shake the bottle well before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP
Discard 12 weeks after first opening.
Open date: _

9. SPECIAL STORAGE CONDITIONS

After first opening, keep the bottle tightly closed and store below 25°C.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

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B. PACKAGE LEAFLET

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

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.

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)
- antipyrine 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, indomethacin, 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 is used to take doses of less than or equal to 10 mg. The syringe can contain a maximum of 1 ml. It has lines that indicate 0.1 ml increases and is marked at 0.5 and 1.0 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 can contain up to 5 ml. It has lines that indicate 0.1 ml increases and is labelled at 1 ml intervals. This syringe should be used to measure doses of more than 10 mg.

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
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:

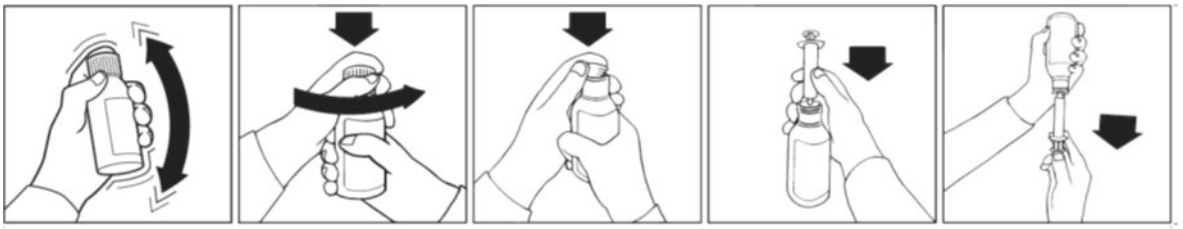

Figure 1 **Figure 2** **Figure 3** **Figure 4** **Figure 5**

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 over dose.

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)
- Pruritis (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 the national reporting system listed in Appendix V. 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.

Marketing Authorisation Holder
Nova Laboratories Ireland Limited
3rd Floor Ulysses House
Foley Street, Dublin 1
D01 W2T2
Ireland

Manufacturer
Pronav Clinical Ltd.
Unit 5
Dublin Road Business Park
Carraroe, Sligo
F91 D439
Ireland

This leaflet was last revised in

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.