SCHEDULING STATUS

S3

1 NAME OF THE MEDICINE

AIRATHON™ 10 mg Film-coated Tablets

AIRATHON™ 5 mg Chewable Tablets

AIRATHON™ 4 mg Chewable Tablets

AIRATHON™ SPRINKLES

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

AIRATHON 10 mg Film-coated Tablets: Each 10 mg film-coated tablet contains 10,4 mg montelukast sodium which is the molar equivalent to 10,0 mg of free acid.

Contains sugar (lactose monohydrate).

AIRATHON 5 mg Chewable Tablets: Each 5 mg chewable tablet contains 5,2 mg montelukast sodium which is the molar equivalent to 5,0 mg of free acid.

Contains sugar (mannitol and aspartame).

AIRATHON 4 mg Chewable Tablets: Each 4 mg chewable tablet contains 4,2 mg montelukast sodium equal to the molar equivalent of 4,0 mg of free acid.

Contains sugar (mannitol and aspartame).

AIRATHON SPRINKLES: Each packet contains 4,2 mg montelukast sodium equal to the molar equivalent of 4,0 mg of free acid.

Contains sugar (mannitol).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

AIRATHON 10 mg Film-coated Tablets: A beige, rounded square film-coated tablet with '117' engraved on one side of the tablet.

AIRATHON 5 mg Chewable Tablets: A pink, round, biconvex tablet with '275' engraved on one side of the tablet.

AIRATHON 4 mg Chewable Tablets: A pink, oval, biconvex tablet with a cherry taste and odour. '711' is engraved on one side of the tablet.

AIRATHON SPRINKLES: White, granular, coarse, free-flowing homogenous solid, with no extraneous particles present.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

AIRATHON 10 mg Film-coated Tablets are indicated in adults and children 15 years of age and older for the prophylaxis and chronic treatment of atopic asthma.

In those adult asthmatic patients, in whom AIRATHON is indicated in asthma, AIRATHON may also provide some symptomatic relief of seasonal allergic rhinitis.

AIRATHON 5 mg Chewable Tablets are indicated in paediatric patients over 6 years of age for the prophylaxis and chronic treatment of atopic asthma.

AIRATHON 4 mg Chewable Tablets and AIRATHON SPRINKLES are indicated in paediatric patients 2 to 5 years of age for the prophylaxis and chronic treatment of atopic asthma.

4.2 Posology and method of administration

AIRATHON should be taken once daily in the evening. AIRATHON can be taken with or without food.

AIRATHON 10 mg Film-coated Tablets

Adults and children 15 years of age and older with atopic asthma

One 10 mg film-coated tablet daily. Clinical studies in adults 15 years of age and older did not demonstrate additional clinical benefit to montelukast doses above 10 mg once daily.

AIRATHON 5 mg Chewable Tablets

Paediatric patients 6 to 14 years of age with atopic asthma

One 5 mg chewable tablet daily.

AIRATHON 4 mg Chewable Tablets

Paediatric patients 2 to 5 years of age with atopic asthma

One 4 mg chewable tablet daily.

AIRATHON SPRINKLES

Paediatric patients 2 to 5 years of age with atopic asthma

One packet of SRINKLES daily.

AIRATHON SPRINKLES can be administered either directly into the mouth, or mixed with a spoonful of cold or room temperature soft food (e.g. apple sauce). The packet should only be opened directly before use, and the full dose of AIRATHON SPRINKLES must be

administered immediately (within 15 minutes). Once mixed with food, AIRATHON SPRINKLES must not be stored for future use. AIRATHON SPRINKLES are not intended to be dissolved in liquid. However, liquids may be taken subsequent to administration.

A therapeutic effect of AIRATHON on parameters of asthma control occurs within one day.

Patients should be advised to continue taking AIRATHON while their asthma is controlled, as well as during periods of worsening asthma.

No dosage adjustment is necessary for the elderly, paediatric patients, for patients with renal insufficiency, or mild-to-moderate hepatic impairment.

Therapy with AIRATHON in relation to other treatments for asthma

AIRATHON can be added to a patient's existing treatment regimen.

Reduction in concomitant therapy

Bronchodilator Treatments: AIRATHON can be added to the treatment regimen of patients who are not adequately controlled on bronchodilator alone. When a clinical response is evident (usually after the first dose), the patient's bronchodilator therapy may be reduced as tolerated.

Inhaled Corticosteroids: A reduction in the corticosteroid dose can be made as tolerated. The dose should be reduced gradually with medical supervision. AIRATHON should not be abruptly substituted for inhaled corticosteroids.

4.3 Contraindications

- Hypersensitivity to montelukast or to any component of AIRATHON.

AIRATHON 10 mg Film-coated Tablets

- Children below the age of 15 years as safety and efficacy have not been demonstrated.

AIRATHON 5 mg Chewable Tablets

- Children below the age of 6 years, as safety and efficacy have not been demonstrated.

AIRATHON 4 mg Chewable Tablets and SPRINKLES

- Children below the age of 2 years, as safety and efficacy have not been demonstrated.

4.4 Special warnings and precautions for use

AIRATHON is not indicated in the reversal of bronchospasm in acute asthma attacks, including status asthmaticus as the efficacy of AIRATHON has not been established for the treatment of acute asthma attacks.

Eosinophilic conditions

Patients on therapy with AIRATHON may present with eosinophilia, sometimes presenting with clinical features of vasculitis consistent with Churg-Strauss syndrome, a condition which is often treated with systemic corticosteroid therapy. These events usually, but not always, have been associated with the reduction of oral corticosteroid therapy. Medical practitioners should be on the alert for patients presenting with eosinophilia, vasculitic rash, worsening of pulmonary symptoms, cardiac complications, and/or neuropathy.

Neuropsychiatric events

Neuropsychiatric events have been reported in adult, adolescent and paediatric patients taking AIRATHON.

Post-marketing reports with AIRATHON use include agitation, aggressive behaviour or hostility, anxiousness, depression, disorientation, disturbance in attention, abnormal dreams, hallucinations, insomnia, irritability, memory impairment, restlessness, somnambulism, suicidal ideation and behaviour (including suicide), tic and tremor.

Patients and medical practitioners should be alert for neuropsychiatric events. Patients should be instructed to notify their medical practitioners if these changes occur. Medical practitioners should carefully evaluate the risks and benefits of continuing treatment with AIRATHON if such events occur.

Hypersensitivity to aspirin

Patients with a known hypersensitivity to aspirin should continue avoiding aspirin and non-steroidal anti-inflammatory drugs (NSAIDs) while taking AIRATHON. Although AIRATHON is effective in improving airway function in asthmatics, it has not been demonstrated to reduce the bronchoconstrictor response to aspirin or other NSAIDs in aspirin-sensitive asthmatic patients.

Hepatic impairment

The metabolism of montelukast may be decreased in patients with mild to moderate hepatic impairment and clinical evidence of cirrhosis. The half-life may be slightly prolonged; however, dosage adjustment is not necessary. No data are available for patients with severe hepatic impairment.

General

AIRATHON is not indicated for use in the reversal of bronchospasm in acute asthma attacks, including status asthmaticus. Patients should be advised to have appropriate rescue

medication available. During acute exacerbations of asthma, therapy with AIRATHON can be continued.

Patients should be advised to take AIRATHON daily as prescribed, even if they are asymptomatic, as well as during periods of worsening of asthma, and to contact their medical practitioners if their asthma is not well controlled. Medical attention should be sought if more than the prescribed maximum number of inhalations of short-acting bronchodilator treatment for a 24-hour period, are needed.

AIRATHON should not be used as monotherapy for the prophylactic treatment of exercise-induced bronchospasm. Patients should continue with their usual inhaled preventer therapy and have a short-acting inhaled beta agonist available for rescue, should they experience exacerbations of asthma after exercise.

AIRATHON should not be abruptly substituted for inhaled or oral corticosteroids. The dose of the corticosteroid therapy may be gradually tapered, under medical supervision.

To ensure safe and appropriate use, patients should be advised to read the section on “Warnings and precautions” in the Patient Information Leaflet.

AIRATHON 10 mg Film-coated Tablets

Galactose intolerance

AIRATHON 10 mg Film-coated Tablets contains lactose. Patients with the rare hereditary conditions of galactose intolerance e.g., galactosaemia, Lapp lactose deficiency or glucose-galactose malabsorption should not take AIRATHON 10 mg Film-coated tablets.

AIRATHON 4 mg and 5 mg Chewable Tablets

Phenylalanine

Phenylketonurics: Phenylketonuric patients should be informed that the chewable tablets contain phenylalanine (a component of aspartame): 0,842 mg per 5 mg chewable tablet and 0,674 mg per 4mg chewable tablet. It may be harmful for patients with phenylketonuria.

4.5 Interaction with other medicines and other forms of interaction

AIRATHON may be administered together with other therapies routinely used in the prophylaxis and chronic treatment of atopic asthma, and seasonal allergic rhinitis.

In medicine interaction studies, the recommended clinical dose of montelukast did not have clinically important effects on the pharmacokinetics of the following medicines: theophylline, prednisone, prednisolone, oral contraceptives (ethinyl oestradiol/norethindrone 35 mcg /1 mg), digoxin and warfarin.

The area under the plasma concentration - time curve (AUC) for montelukast was decreased approximately 40 % in subjects with co-administration of phenobarbitone. No dosage adjustment for AIRATHON is recommended. Clinical monitoring is recommended when potent hepatic enzyme inducers (such as ritonavir, phenytoin, phenobarbitone, rifampicin, or *St John's wort* are given with AIRATHON).

In vitro studies have shown that montelukast is an inhibitor of isoenzyme CYP2C8. However, data from an interaction study involving montelukast and rosiglitazone (a substrate representative of medicines primarily metabolised by isoenzyme CYP2C8) demonstrated that montelukast did not significantly inhibit isoenzyme CYP2C8 *in vivo.* Therefore, AIRATHON is not anticipated to alter the metabolism of medicines metabolised by isoenzyme (CYP2C8) (e.g. paclitaxel, rosiglitazone, and repaglinide.)

In vitro studies have shown that montelukast is a substrate of CYP2C8, CYP2C9, and CYP3A4. Data from an interaction study involving montelukast and gemfibrozil (an inhibitor of both CYP2C8 and CYP2C9) demonstrated that gemfibrozil increased the systemic exposure of montelukast by 4,4-fold. Co-administration of itraconazole, a strong CYP3A4 inhibitor, with gemfibrozil and montelukast did not further increase the systemic exposure of montelukast. The effect of gemfibrozil on systemic exposure of montelukast is not considered to be clinically meaningful based on clinical safety data with doses greater than the 10 mg approved dose in adults (e.g., 200 mg/day to adult patients for 22 weeks, and up to 900 mg/day to patients for approximately one week) where clinically important adverse experiences were not observed. Therefore, no dosage adjustment of AIRATHON is required upon co-administration with gemfibrozil. Based on *in vitro* data, important interactions with other known inhibitors of CYP2C8 (e.g., trimethoprim) are not anticipated. In addition, co-administration of montelukast with itraconazole alone resulted in no significant increase in the systemic exposure of montelukast.

4.6 Pregnancy and lactation

Pregnancy

The safety of AIRATHON in pregnant and lactating women has not been established.

Available data from published prospective and retrospective cohort studies with montelukast use in pregnant women evaluating major birth defects have not established a drug-associated risk. Available studies have methodologic limitations, including small sample size, in some cases retrospective data collection, and inconsistent comparator groups.

Breastfeeding

It is not known if AIRATHON is excreted in human milk. Women using AIRATHON should not breastfeed their infants.

4.7 Effects on ability to drive and use machines

AIRATHON may cause side effects such as dizziness or drowsiness, which may affect the ability to drive. Patients should therefore be advised not to drive or operate machinery until their individual susceptibility to AIRATHON is known.

4.8 Undesirable effects

Side effects generally did not require discontinuation of therapy.

The following medicine related adverse reactions in placebo-controlled clinical studies were reported in patients with asthma treated with AIRATHON and at a greater incidence than in patients treated with placebo. The adverse reactions are listed by system organ class and frequency category.

Frequency categories: 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)

	Adult and Adolescent Patients 15 years and older (two 12 week studies; n=795)		**Paediatric Patients 6 to 14 years old (one 8 week study; n=201)**		**Paediatric Patients 2 to 5 years old (one 12 week study; n=461)**	
System Organ Class	**Adverse Reaction**	**Frequency**	**Adverse Reaction**	**Frequency**	**Adverse Reaction**	**Frequency**
Ear and labyrinth			Vertigo	Uncommon [a]		

disorders						
Eye disorders	Blepharospasm	Uncommon[a]				
					Mydriasis	Uncommon[a]
Gastrointestinal disorders			Abdominal discomfort	Uncommon[a]		
	Abdominal pain	Uncommon				
	Abdominal pain upper	Uncommon				
	Bowel movement irregularity	Uncommon[a]				
	Diarrhoea	Uncommon			Diarrhoea	Uncommon[a]
	Dry mouth	Uncommon				
	Dyspepsia	Uncommon				
	Flatulence	Uncommon	Flatulence	Uncommon[a]		
	Nausea	Uncommon				
	Salivary hypersecretion	Uncommon[a]				
	Vomiting	Uncommon				
General disorders and	Chest pain	Uncommon[a]				

administration site conditions						
	Fatigue	Uncommon				
	Irritability	Uncommon[a]				
					Thirst	Common
Immune System disorders					Decreased immune responsiveness	Uncommon[a]
Investigations	Alanine aminotransferase increased	Uncommon				
	Aspartate aminotransferase increased	Uncommon			Aspartate aminotransferase increased	Uncommon
					Eosinophil count increased	Uncommon[a]
					Haematocrit decreased	Uncommon
					Haemoglobin	Uncommon

					decreased	
	White blood cell count decreased	Uncommon			White blood cell count decreased	Uncommon[a]
Metabolism and nutrition disorders	Increased appetite	Uncommon[a]				
Musculoskeletal and connective tissue disorders	Arthralgia	Uncommon				
	Back pain	Uncommon[a]	Back pain	Uncommon[a]		
	Muscle spasms	Uncommon[a]				
	Muscular weakness	Uncommon[a]				
	Myalgia	Uncommon[a]	Myalgia	Uncommon[a]		
	Pain in extremity	Uncommon[a]				
Nervous system disorders	Dizziness	Uncommon	Dizziness	Uncommon[a]		

	Headache	Common	Headache	Common	Headache	Uncommon[a]
	Hypersomnia	Uncommon				
					Paraesthesia	Uncommon[a]
	Somnolence	Uncommon				
	Tremor	Uncommon[a]	Tremor	Uncommon[a]		
Psychiatric disorders	Insomnia	Uncommon	Insomnia	Uncommon		
	Libido decreased	Uncommon[a]				
			Mood swings	Uncommon[a]		
Renal and urinary disorders					Enuresis	Uncommon[a]
Respiratory, thoracic and mediastinal disorders	Asthma	Uncommon			Asthma	Uncommon[a]
	Cough	Uncommon[a]				
	Dysphonia	Uncommon[a]			Dysphonia	Uncommon[a]
	Dyspnoea	Uncommon				

		[a]				
			Epistaxis	Uncommon [a]		
	Oropharyngeal pain	Uncommon [a]				
	Postnasal drip	Uncommon [a]				
	Respiratory tract congestion	Uncommon [a]				
	Rhinitis allergic	Uncommon [a]				
Skin and subcutaneous tissue disorders	Acne	Uncommon [a]				
	Night sweats	Uncommon [a]				
					Pruritus generalised	Uncommon[a]
	Rash	Uncommon				
	Rash pruritic	Uncommon [a]				
Vascular disorders	Hypertension	Uncommon [a]			Hypertension	Uncommon[a]
[a] Reported in 1 patient in the montelukast group.						

With prolonged treatment in clinical trials with a limited number of patients for up to 2 years for adults, and up to 6 months for paediatric patients 6 to 14 years of age, the safety profile did not change.

Patients on therapy with AIRATHON may present with systemic eosinophilia, sometimes presenting with clinical features of vasculitis consistent with Churg-Strauss syndrome (see section 4.4).

Post-Marketing Experience

The following side effects have been reported in post-marketing use:

Infections and infestations: upper respiratory tract infections

Blood and lymphatic system disorders: increased bleeding tendency, thrombocytopenia

Immune system disorders: hypersensitivity reactions including anaphylaxis, hepatic eosinophilic infiltration

Psychiatric disorders: abnormal dreams, dysphemia (stuttering), hallucinations, agitation including aggressive behaviour or hostility, anxiousness, depression, disorientation, disturbance in attention, insomnia, memory impairment, obsessive-compulsive symptoms, psychomotor hyperactivity (including irritability, restlessness, and tremor) somnambulism, suicidal ideation and behaviour (suicidality), tic

Nervous system disorders: dizziness, drowsiness, paraesthesia/hypoaesthesia, seizure

Cardiac disorders: palpitations

Respiratory, thoracic and mediastinal disorders: epistaxis, pulmonary eosinophilia, and Churg-Strauss syndrome

Gastrointestinal disorders: diarrhoea, dyspepsia, nausea, vomiting

Hepatobiliary disorders: increased alanine aminotransferase (ALT) and aspartate aminotransferase (AST), hepatitis (including cholestatic, hepatocellular and mixed-pattern liver injury)

Skin and subcutaneous tissue disorders: angioedema, bruising, erythema multiforme, erythema nodosum, pruritus, rash, urticaria

Musculoskeletal and connective tissue disorders: arthralgia, myalgia, including muscle cramps

Renal and urinary disorders: enuresis in children

General disorders and administration sites conditions: oedema, pyrexia, asthenia/fatigue

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose

There were no adverse experiences reported in the majority of overdosage reports. The most frequently occurring adverse experiences included abdominal pain, somnolence, thirst, headache, vomiting and psychomotor hyperactivity.

In chronic asthma studies, AIRATHON has been administered at doses up to 200 mg/day to adult patients for 22 weeks and in short-term studies, up to 900 mg/day to patients for approximately one week without clinically important adverse experiences.

No specific information is available on the treatment of overdosage with AIRATHON.

Treatment is symptomatic and supportive.

It is not known whether montelukast is dialysable by either peritoneal or haemodialysis.

5 PHARMACOLOGICAL PROPERTIES

A.10.2.2 Other anti-asthmatics, leukotriene receptor antagonist

5.1 Pharmacodynamic Properties

Montelukast is a leukotriene receptor antagonist.

Montelukast inhibits airway cysteinyl leukotriene receptors, as demonstrated by its ability to inhibit bronchoconstriction due to inhaled LTD_4 in asthmatic patients.

Montelukast binds with high affinity and selectivity to the $CysLT_1$ receptor. Montelukast inhibits physiological actions of LTC_4, LTD_4, and LTE_4 at the $CysLT_1$ receptor without agonist activity.

5.2 Pharmacokinetic Properties

Absorption

Montelukast is absorbed following oral administration.

The co-administration of apple sauce or a high fat, high kilojoule meal with the oral granule formulation did not have a clinically meaningful effect on the pharmacokinetics of montelukast as determined by AUC.

For the 10 mg film-coated tablet, the mean peak plasma concentration (C_{max}) is achieved 3 hours (T_{max}) after administration in adults in the fasted state. The mean oral bioavailability is 64 %. The oral bioavailability and C_{max} are not influenced by a standard meal.

For the 5 mg chewable tablet, the C_{max} is achieved 2 hours after administration in adults in the fasted state. The mean oral bioavailability is 73 %. Food does not have a clinically important influence with chronic administration.

For the 4 mg chewable tablet, C_{max} is achieved 2 hours after administration in paediatric patients 2 to 5 years of age in the fasted state.

Safety and efficacy were demonstrated in clinical studies where the 4 mg chewable tablet and SPRINKLES were administered without regard to the timing of food ingestion.

Distribution

Montelukast is more than 99 % bound to plasma proteins. The steady-state volume of distribution of montelukast averages 8 to 11 litres. Studies in rats with radio-labelled montelukast indicate minimal distribution across the blood-brain barrier. In addition, concentrations of radio-labelled material at 24 hours post dose were minimal in all other tissues.

Metabolism

Montelukast is extensively metabolised in the liver. In studies with therapeutic doses, plasma concentrations of metabolites of montelukast are undetectable at steady state in adults and paediatric patients.

In vitro studies using human liver microsomes indicate that cytochrome P450 isoenzymes CYP2CB, CYP3A4, and CYP2C9 are involved in the metabolism of montelukast. Based on further *in vitro* results in human liver microsomes, therapeutic plasma concentrations of montelukast do not inhibit cytochrome P450, isoenzymes 3A4, 2C9, 1A2, 2A6, 2C19 or 2D6.

Elimination

The plasma clearance of montelukast averages 45 mL/min in healthy adults. Following an oral dose of radio-labelled montelukast, 86 % of the radioactivity was recovered in 5 day faecal collections and less than 0,2 % was recovered in urine. Coupled with estimates of montelukast oral bioavailability, this indicates montelukast and its metabolites are excreted almost exclusively via the bile.

In several studies, the mean plasma half-life of montelukast ranged from 2,7 to 5,5 hours in healthy young adults. The pharmacokinetics of montelukast are nearly linear for oral doses up to 50 mg. No difference in pharmacokinetics was noted between dosing in the morning or in the evening. During once-daily dosing with 10 mg montelukast, there is little accumulation of the parent molecule in plasma (approximately 14 %).

Special Populations

Hepatic Insufficiency

Patients with mild-to-moderate hepatic insufficiency and clinical evidence of cirrhosis had evidence of decreased metabolism of montelukast resulting in approximately 41 % higher mean montelukast area under the plasma concentration curve (AUC) following a single 10 mg dose. The elimination of montelukast is slightly prolonged compared with that in healthy subjects (mean half-life, 7,4 hours).

No dosage adjustment is required in patients with mild-to-moderate hepatic insufficiency.

There are no clinical data in patients with severe hepatic insufficiency (Child-Pugh score >9).

Renal Insufficiency

Since montelukast and its metabolites are not excreted in the urine, the pharmacokinetics of montelukast were not evaluated in patients with renal insufficiency. No dosage adjustment is recommended in these patients.

Elderly

The pharmacokinetic profile and the oral bioavailability of a single 10 mg oral dose of montelukast are similar in elderly and younger adults. The plasma half-life of montelukast is slightly longer in the elderly. No dosage adjustment in the elderly is required.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

AIRATHON 10 mg Film-coated Tablets

Inactive ingredients: Carnauba wax, croscarmellose sodium, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, methyl hydroxypropyl cellulose, microcrystalline cellulose, red ferric oxide, titanium dioxide, yellow ferric oxide.

AIRATHON 5 mg Film-coated Tablets

Inactive ingredients: Artificial cherry flavour, aspartame, croscarmellose sodium, hydroxypropyl cellulose, magnesium stearate, mannitol, microcrystalline cellulose, red ferric oxide.

AIRATHON 4 mg Chewable Tablets

Inactive ingredients: Artificial cherry flavour, aspartame, croscarmellose sodium, hydroxypropyl cellulose, magnesium stearate, mannitol, microcrystalline cellulose, red ferric oxide.

AIRATHON SPRINKLES

Inactive ingredients: Hydroxypropyl cellulose, magnesium stearate, mannitol.

6.2 Incompatibilities

Not Applicable

6.3 Shelf-life

Not Applicable

6.4 Special precautions for storage

Store at or below 30 °C, protected from moisture and light.

Store all medicines out of reach of children.

AIRATHON SPRINKLES

The packet should not be opened until directly before use. The full dose must be administered immediately (within 15 minutes). Once mixed with food, it must not be stored for future use.

6.5 Nature and contents of container

AIRATHON 10 mg Film-coated Tablets are available in OPA/Al/PVC blister packs of 28 or 30.

AIRATHON 5 mg Chewable Tablets are available in OPA/Al/PVC blister packs of 28 or 30.

AIRATHON 4 mg Chewable Tablets are available in OPA/Al/PVC blister packs of 28 or 30.

AIRATHON SPRINKLES (500 mg net weight) is available in low density polyethylene/aluminium /polyester film foil packets in pack sizes of 28 per carton.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Any unused medicinal product should be disposed of in accordance with local requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

Organon South Africa (Pty) Ltd

Spaces, 1st Floor, 22 Magwa Crescent,

Gateway West, Waterfall City,

Midrand, 2090,

South Africa

8 REGISTRATION NUMBER(S)

AIRATHON 10 mg Film-coated tablets: 44/10.2.2/0668

AIRATHON 5 mg Chewable Tablets: 44/10.2.2/0667

AIRATHON 4 mg Chewable Tablets: 44/10.2.2/0666

AIRATHON SPRINKLES: 44/10.2.2/0669

9 DATE OF FIRST AUTHORISATION

Date on the registration certificate:

AIRATHON 10 mg: 27 July 2012

AIRATHON 5 mg: 27 July 2012

AIRATHON 4 mg: 27 July 2012

AIRATHON SPRINKLES: 27 July 2012

10 DATE OF REVISION OF THE TEXT

27 February 2022

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