SCHEDULING STATUS: S4

1. NAME OF THE MEDICINE:

RELVAR ELLIPTA 92/22 µg inhalation powder, pre-dispensed

RELVAR ELLIPTA 184/22 µg inhalation powder, pre-dispensed

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each pre-dispensed dose contains either 100/25 µg or 200/25 µg of fluticasone furoate/vilanterol (as trifenatate).

Each single inhalation of fluticasone furoate/vilanterol provides a delivered dose of 92/22 µg of fluticasone furoate/vilanterol or 184/22 µg of fluticasone furoate/vilanterol.

Contains sugar (lactose monohydrate 25 mg/dose).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM:

Inhalation powder, pre-dispensed.

The plastic Ellipta inhaler consists of a light grey body, a pale blue mouthpiece cover and a dose counter, packed into a foil laminate tray containing a desiccant packet. The tray is sealed with a peelable foil lid.

The inhaler contains two strips of 30 regularly distributed blisters, each blister containing a single dose of white powder.

4. CLINICAL PARTICULARS:

4.1 Therapeutic indications:

Asthma: RELVAR is indicated for the maintenance, preventive treatment of asthma.

COPD: RELVAR is indicated for the maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD) including chronic bronchitis and/or emphysema and to reduce exacerbations of COPD in patients with an exacerbation history.

4.2 Posology and method of administration:

Posology:

RELVAR is for inhalation only.

RELVAR should be administered once daily either morning or evening but at the same time every day.

After inhalation, patients should rinse their mouth with water without swallowing.

Method of administration:

Asthma:

Patients should be made aware that RELVAR must be used regularly, even when asymptomatic.

If symptoms arise in the period between doses, an inhaled, short-acting beta$_2$-agonist should be taken for immediate relief.

Patients should be regularly re-assessed by a healthcare professional so that the strength of RELVAR they are receiving remains optimal and is only changed on medical advice.

Adults and adolescents aged 12 years and over:

The recommended dose of RELVAR is:

One inhalation of RELVAR 100/25 µg once daily

or

One inhalation of RELVAR 200/25 µg once daily.

A starting dose of RELVAR 100/25 µg should be considered for patients who require a low to mild dose of inhaled corticosteroid in combination with a long acting beta$_2$-agonist.

RELVAR 200/25 µg should be considered for patients who require a higher dose of inhaled corticosteroid in combination with a long acting beta$_2$-agonist.

If patients are inadequately controlled on RELVAR 100/25 µg, consider increasing the dose to 200/25 µg, which may provide additional improvement in asthma control.

Children: The safety and efficacy of RELVAR has not been established in children less than 12 years of age.

COPD:

Adults: The recommended dose of RELVAR is:

One inhalation of RELVAR 100/25 µg once daily.

RELVAR 200/25 µg is not indicated for patients with COPD.

Use and handling:

Refer to Patient Information Leaflet for the step-by-step instructions.

Special populations (asthma and COPD):

Elderly: No dosage adjustment is required in patients over 65 years (see section 5.2).

Renal impairment: No dose adjustment is required for patients with renal impairment (see section 5.2).

Hepatic impairment: A clinical pharmacology study in subjects with mild, moderate and severe hepatic impairment showed up to 3-fold increase in systemic exposure to fluticasone furoate (AUC) (see section 5.2).

Caution should be exercised when dosing patients with hepatic impairment who may be more at risk of systemic adverse reactions associated with corticosteroids.

For patients with moderate (Child Pugh class B) or severe (Child Pugh class C) hepatic impairment the maximum dose is 100/25 µg (see section 4.4).

Children and adolescents:

Do not give RELVAR to children under the age of 12 years for the treatment of asthma, or children and adolescents of any age for the treatment of COPD.

4.3 Contraindications:

RELVAR is contraindicated in patients with severe milk-protein allergy or who have demonstrated hypersensitivity to either fluticasone furoate, vilanterol or any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use:

Exacerbations:

RELVAR should not be used to treat acute asthma symptoms or an acute exacerbation in COPD, for which a short-acting bronchodilator is required. Increasing use of short-acting bronchodilators to relieve symptoms indicates deterioration of control and patients should be reviewed by a medical practitioner.

Patients should not stop therapy with RELVAR, in asthma or COPD, without medical practitioner supervision since symptoms may recur after discontinuation.

Asthma-related adverse events and exacerbations may occur during treatment with RELVAR. Patients should be asked to continue treatment but to seek medical advice if asthma symptoms remain uncontrolled or worsen after initiation of RELVAR.

Paradoxical bronchospasm:

Paradoxical bronchospasm may occur with an immediate increase in wheezing after dosing. This should be treated immediately with a short-acting inhaled bronchodilator. RELVAR should be discontinued immediately, the patient assessed and alternative therapy instituted if necessary.

Cardiovascular effects:

Cardiovascular effects, such as cardiac dysrhythmias e.g., supraventricular tachycardia and extrasystoles may be seen with sympathomimetic medicines, including RELVAR. In a placebo-controlled study in subjects with a history of, or an increased risk of cardiovascular disease, there was no increase in the risk of, cardiovascular events, serious cardiovascular events, or adjudicated cardiovascular deaths in patients receiving RELVAR compared with placebo (see section 4.8). However, RELVAR should be used with caution in patients with cardiovascular disease, or heart rhythm abnormalities, hyperthyroidism or uncorrected hypokalaemia.

Hypokalaemia may occur. Overdosages may cause cardiac effects. High dosages may increase the risk of serious side effects, including cardiac dysrhythmias. This risk is further aggravated if RELVAR is administered concomitantly with other medicines that cause hypokalaemia and cardiac dysrhythmias, or in the presence of hypoxia and acidosis.

The maximum dosage should not be exceeded.

Patients with hepatic impairment:

For patients with moderate (Child Pugh class B) and severe (Child Pugh class C) hepatic impairment, the 100/25 µg dose should be used and patients should be monitored for systemic corticosteroid-related adverse reactions (see section 4.2 and section 5.2).

Patients with diabetes mellitus

There have been reports of increases in blood glucose levels in diabetic patients and this should be considered when prescribing to patients with a history of diabetes mellitus (see section 4.8).

Systemic corticosteroid effects:

Systemic corticosteroid effects may occur, particularly at high doses prescribed for long periods. Systemic effects include, HPA axis suppression, decrease in bone mineral density, growth retardation in children and adolescents, cataract, glaucoma and central serous chorioretinopathy (CSCR).

RELVAR should be administered with caution in patients with pulmonary tuberculosis or in patients with chronic or untreated infections.

Pneumonia:

An increase in pneumonia has been observed in patients with COPD receiving RELVAR. There was also an increased incidence of pneumonias resulting in hospitalisation. In some incidences these pneumonia events were fatal (see section 4.8). Medical practitioners should remain vigilant for the possible development of pneumonia in patients with COPD as the clinical features of such infections overlap with the symptoms of COPD exacerbations. Risk factors for pneumonia in patients with COPD receiving RELVAR include current smokers, patients with a history of prior pneumonia, patients with a body mass index < 25 kg/m^2 and patients with a (forced expiratory volume) FEV_1< 50 % predicted. These factors should be considered when RELVAR is prescribed and treatment should be re-evaluated if pneumonia occurs.

Patients with asthma taking RELVAR 200/25 µg may be at an increased risk of pneumonia compared with those receiving RELVAR 100/25 µg or placebo (see section 4.8). No risk factors were identified.

Contains lactose:

RELVAR contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance e.g., galactosaemia, Lapp lactase deficiency or glucose-galactose malabsorption or fructose intolerance should not use RELVAR (see section 2).

4.5 Interaction with other medicines and other forms of interaction:

Clinically significant medicine interactions mediated by fluticasone furoate or vilanterol at clinical doses are considered unlikely due to the low plasma concentrations achieved after inhaled dosing.

Interaction with beta-blockers: Beta-adrenergic blockers may cause bronchospasms and may weaken or antagonise the effect of beta$_2$-adrenergic agonists. Therefore, concurrent use of both non-selective and selective beta-blockers should be avoided unless there are compelling reasons for their use (see section 4.4).

Interaction with CYP3A4 inhibitors: Fluticasone furoate and vilanterol are both rapidly cleared by extensive first-pass metabolism mediated by the liver enzyme CYP3A4.

Care is advised when co-administering with strong CYP3A4 inhibitors (e.g., ketoconazole, ritonavir) as there is potential for an increased systemic exposure to both fluticasone furoate and vilanterol, which could lead to an increase in the potential for adverse reactions (see section 5.2).

A repeat dose CYP3A4 interaction study was performed in healthy subjects with the fluticasone furoate/vilanterol combination (200/25) and the strong CYP3A4 inhibitor ketoconazole (400 mg). Co-administration increased mean fluticasone furoate AUC(0-24) and C_{max} by 36 % and 33 %, respectively. The increase in fluticasone furoate exposure was associated with a 27 % reduction in 0-24 h weighted mean serum cortisol.

Interaction with P-glycoprotein inhibitors: Fluticasone furoate and vilanterol are both substrates of P-glycoprotein (P-gp). A clinical pharmacology study in healthy subjects with co-administered

vilanterol and the potent P-gp and moderate CYP3A4 inhibitor verapamil did not show any significant effect on the pharmacokinetics of vilanterol. Clinical pharmacology studies with a specific P-gp inhibitor and fluticasone furoate have not been conducted.

4.6 Fertility, pregnancy and lactation:

Safety during pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines:

There have been no studies to investigate the effect of RELVAR on driving performance or the ability to operate machinery.

4.8 Undesirable effects:

Clinical trial data:

Data from clinical trials were used to determine the frequency of adverse reactions associated with RELVAR. In the asthma clinical development program, a total of 7 034 patients were included in an integrated assessment of adverse reactions. In the COPD clinical development program, a total of 6 237 subjects were included in an integrated assessment of adverse reactions.

With the exception of pneumonia and fractures, the safety profile was similar in patients with asthma and COPD. During clinical studies, pneumonia and fractures were more frequently observed in patients with COPD.

These adverse reactions are listed by system organ class and frequency. The following convention has been used for the classification of adverse reactions:

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.

System organ class	Adverse reaction(s)	Frequency
Infections and infestations	Pneumonia*, Upper respiratory tract infection, Bronchitis, Influenza, Candidiasis of mouth and throat	Common
Nervous system disorders	Headache	Very Common
Cardiac disorders	Extrasystoles**	Uncommon
Respiratory, thoracic & mediastinal disorders	Nasopharyngitis Oropharyngeal Pain, Sinusitis, Pharyngitis	Very Common Common
Gastrointestinal disorders	Abdominal Pain	Common
Musculoskeletal and connective tissue disorders	Arthralgia, Back Pain, Fractures***	Common
General disorders and administration site conditions:	Pyrexia.	Common

Description of selected adverse reactions:

* ***Pneumonia*** (see section 4.4): In two replicate 12 month studies in a total of 3 255 patients with COPD (mean post-bronchodilator screening FEV_1 45 % of predicted, standard deviation (SD) 13 %) who had experienced a COPD exacerbation in the previous year, there was a higher incidence of pneumonia (6 % - 7 %) reported in patients receiving the fluticasone furoate (at strengths of 50, 100, and 200 µg)/vilanterol 25 µg combination than in those receiving vilanterol 25 µg alone (3 %). Pneumonia which required hospitalisation occurred in 3 % of patients receiving RELVAR (all strengths) and in < 1 % of patients receiving vilanterol. In these studies, nine fatal cases of pneumonia were reported. Of these, seven were reported during treatment with

RELVAR 200/25 µg, one during treatment with RELVAR 100/25 µg and one post-treatment with vilanterol monotherapy.

In SUMMIT, a multi-centre, randomised study (HZC113782), 16 568 subjects received RELVAR 100/25 µg, fluticasone furoate 100 µg, vilanterol 25 µg, or placebo for a mean of 1,7 years. Subjects had moderate COPD (mean post-bronchodilator screening FEV_1 60 % of predicted, SD 6 %) and a history of, or an increased risk of, cardiovascular disease. The adverse events of pneumonia are noted in the table below.

On-treatment events	**Number (%) of subjects [event rate per 1 000 treatment years]**			
	FF/VI 100/25 N = 4 140	**FF 100 N = 4 157**	**VI 25 N = 4 140**	**Placebo N = 4 131**
Pneumonia	237 (6) [39,5]	228 (5) [42,4]	163 (4) [27,7]	214 (5) [38,4]
Serious pneumonia	140 (3) [22,4]	146 (4) [25,1]	104 (3) [16,4]	127 (3) [22,2]
Adjudicated pneumonia deaths	13 (<1) [1,8]	10 (<1) [1,5]	6 (<1) [0,9]	9 (<1) [1,4]

In an integrated analysis of 11 studies in asthma (7 034 patients), the incidence of pneumonia (adjusted for exposure, due to low numbers and limited number of patients on placebo) seen with RELVAR 100/25 µg strength (9,6/1000 patient years) was similar to placebo (8,0/1000 patient years). There was a higher incidence of pneumonia in the 200/25 µg strength (18,4/1000 patient years) compared to the 100/25 µg strength.

** **Cardiovascular events (see section 4.4)**: For the SUMMIT study (see description above), cardiovascular adverse events are noted in the table below.

On-treatment events	Number (%) of subjects [event rate per 1 000 treatment years]			
	FF/VI 100/25 N = 4 140	**FF 100 N = 4 157**	**VI 25 N = 4 140**	**Placebo N = 4 131**
Cardiovascular	735 (18) [163]	699 (17) [157]	707 (17) [157]	695 (17) [164]
Serious cardiovascular	350 (8) [64,5]	320 (8) [58,1]	337 (8) [59,2]	318 (8) [63,2]
Adjudicated cardiovascular deaths	82 (2) [11,7]	80 (2) [11,6]	90 (2) [12,9]	86 (2) [13,0]

*** ***Fractures:*** In two replicate 12-month studies in a total of 3 255 patients with COPD the incidence of bone fractures overall was low in all treatment groups, with a higher incidence in all RELVAR groups (2 %) compared with the vilanterol 25 µg group (< 1 %). Although there were more fractures in the RELVAR groups compared with the vilanterol 25 µg group, fractures typically associated with corticosteroid use (e.g., spinal compression/thoracolumbar vertebral fractures, hip and acetabular fractures) occurred in < 1 % of the RELVAR and vilanterol treatment arms.

For the SUMMIT study (see description above), fractures are noted in the table below.

On-treatment events	Number (%) of subjects [event rate per 1 000 treatment years]			
	FF/VI 100/25 N = 4 140	FF 100 N = 4 157	VI 25 N = 4 140	Placebo N = 4 131
All fractures	82 (2) [13,6]	66 (2) [12,8]	74 (2) [13,2]	69 (2) [11,5]
Fractures commonly associated with ICS use	23 (<1) [3,4]	24 (<1) [3,9]	17 (<1) [2,4]	13 (<1) [2,1]

In an integrated analysis of 11 studies in asthma (7 034 patients), the incidence of fractures was < 1 %, and usually associated with trauma.

Post-marketing data:

System organ class	Adverse reaction(s)	Frequency
Immune system disorders:	Hypersensitivity reactions including anaphylaxis, angioedema, rash and urticaria	Less Frequent
Metabolism and nutrition disorders:	Hyperglycaemia	Uncommon
Psychiatric disorders:	Anxiety	Less Frequent
Nervous system disorders:	Tremor	Less Frequent
Cardiac disorders	palpitations, tachycardia	Less Frequent
Respiratory, thoracic & mediastinal disorders	Paradoxical bronchospasm	Less Frequent
Musculoskeletal and connective tissue disorders:	Muscle Spasms.	Common

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of RELVAR ELLIPTA is important. It allows continued monitoring of the benefit/risk balance of RELVAR ELLIPTA. Healthcare providers 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:

Symptoms and signs:

An overdose of RELVAR may produce signs and symptoms due to the individual components' actions, including those seen with overdose of other beta$_2$-agonists and consistent with the known inhaled corticosteroid class effects (see section 4.4).

Treatment:

There is no specific treatment for an overdose with RELVAR. If overdose occurs, the patient should be treated supportively with appropriate monitoring as necessary.

Cardio-selective beta-blockade should only be considered for profound vilanterol overdose effects that are clinically concerning and unresponsive to supportive measures. Cardio-selective beta-blocking medicines should be used with caution in patients with a history of bronchospasm.

Further management should be as clinically indicated or as recommended by the national poison centre, where available.

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties:

Category and class: A 21.5.1 Corticosteroids and analogues

Fluticasone furoate and vilanterol represent two classes of medications (a synthetic corticosteroid and a selective, long-acting beta$_2$-receptor agonist).

Fluticasone furoate: Fluticasone furoate is a synthetic trifluorinated corticosteroid with anti-inflammatory activity. The precise mechanism through which fluticasone furoate affects asthma and COPD symptoms is not known. Corticosteroids have been shown to have a wide range of actions on multiple cell types (e.g., eosinophils, macrophages, lymphocytes) and mediators (e.g., cytokines and chemokines involved in inflammation).

Vilanterol trifenatate: Vilanterol trifenatate is a selective long-acting, beta$_2$-adrenergic agonist (LABA).

The pharmacologic effects of beta$_2$-adrenoceptor agonists, including vilanterol trifenatate, are at least in part attributable to stimulation of intracellular adenylate cyclase, the enzyme that catalyses the conversion of adenosine triphosphate (ATP) to cyclic-3',5'-adenosine monophosphate (cyclic AMP). Increased cyclic AMP levels cause relaxation of bronchial smooth muscle and inhibition of release of mediators of immediate hypersensitivity from cells, especially from mast cells.

Molecular interactions occur between corticosteroids and LABAs, whereby steroids activate the beta$_2$-receptor gene, increasing receptor number and sensitivity; and LABAs prime the glucocorticoid receptor for steroid-dependent activation and enhance cell nuclear translocation.

5.2 Pharmacokinetic properties:

Absorption: The absolute bioavailability for fluticasone furoate and vilanterol when administered by inhalation as fluticasone furoate/vilanterol was on average 15,2 % and 27,3 %, respectively. The oral bioavailability of both fluticasone furoate and vilanterol was low, on average 1,26 % and < 2 %, respectively. Systemic exposure for fluticasone furoate and vilanterol following inhaled administration is primarily due to absorption of the inhaled portion of the dose delivered to the lung.

Distribution: Following intravenous dosing, both fluticasone furoate and vilanterol are extensively distributed with average volumes of distribution at steady state of 661 L and 165 L, respectively. Both fluticasone furoate and vilanterol have a low association with red blood cells. *In vitro* plasma protein binding in human plasma of fluticasone furoate and vilanterol was on average > 99,6 % and 93,9 %, respectively. There was no decrease in the extent of *in vitro* plasma protein binding in subjects with renal or hepatic impairment.

Fluticasone furoate and vilanterol are substrates for P-gp, however, concomitant administration of fluticasone furoate/vilanterol with P-gp inhibitors is considered unlikely to alter fluticasone furoate or vilanterol systemic exposure since they are both well absorbed molecules.

Metabolism: Based on *in vitro* data, the major routes of metabolism of both fluticasone furoate and vilanterol in human are mediated primarily by CYP3A4.

Fluticasone furoate is primarily metabolised through hydrolysis of the S-fluoromethyl carbothioate group to metabolites with significantly reduced corticosteroid activity.

Vilanterol is primarily metabolised by O-dealkylation to a range of metabolites with significantly reduced β_1- and β_2-agonist activity.

Elimination: Following oral administration, fluticasone furoate was eliminated in humans mainly by metabolism with metabolites being excreted almost exclusively in faeces, with < 1 % of the recovered radioactive dose eliminated in the urine. The apparent plasma elimination half-life of fluticasone furoate following inhaled administration of fluticasone furoate/vilanterol was, on average, 24-hours.

Following oral administration, vilanterol was eliminated in humans mainly by metabolism followed by excretion of metabolites in urine and faeces approximately 70 % and 30 % of the radioactive dose

respectively. The apparent plasma elimination half-life of vilanterol following inhaled administration of fluticasone furoate/vilanterol was, on average, 2,5 hours.

Special patient populations:

Race: In subjects with asthma or COPD estimates of fluticasone furoate $AUC_{(0-24)}$ for East Asian, Japanese and Southeast Asian subjects (12-14 % subjects) were up to 53 % higher on average compared with Caucasian subjects. However, there was no evidence for the higher systemic exposure in these populations to be associated with greater effect on 24-hour urinary cortisol excretion.

On average, vilanterol C_{max} is estimated to be 220-287 % higher and $AUC_{(0-24)}$ comparable for those subjects from an Asian heritage compared with subjects from other racial groups. However, there was no evidence that this higher vilanterol C_{max} resulted in clinically significant effects on heart rate.

Children: In adolescents (12 years or older), there are no recommended dose modifications.

The pharmacokinetics of fluticasone furoate/vilanterol in patients less than 12 years of age has not been studied. The safety and efficacy of fluticasone furoate/vilanterol in children under the age of 12 years has not yet been established.

Elderly: The effects of age on the pharmacokinetics of fluticasone furoate and vilanterol were determined in phase III studies in COPD and asthma. There was no evidence for age (12-84) to affect the PK of fluticasone furoate and vilanterol in subjects with asthma.

There was no evidence for age to affect the PK of fluticasone furoate in subjects with COPD while there was an increase (37 %) in $AUC_{(0-24)}$ of vilanterol over the observed age range of 41 to 84 years. For an elderly subject (aged 84 years) with low bodyweight (35 kg) vilanterol $AUC_{(0-24)}$ is predicted to be 35 % higher than the population estimate (subject with COPD aged 60 years and bodyweight of 70 kg), whilst C_{max} was unchanged.

Renal impairment: A clinical pharmacology study of fluticasone furoate/vilanterol showed that severe renal impairment (creatinine clearance < 30 mL/min) did not result in significantly greater exposure to fluticasone furoate or vilanterol or more marked corticosteroid or $beta_2$-agonist systemic effects compared with healthy subjects. No dose adjustment is required for patients with renal impairment.

The effects of haemodialysis have not been studied.

Hepatic impairment: Following repeat dosing of fluticasone furoate/vilanterol for 7 days, there was an increase in fluticasone furoate systemic exposure (up to three-fold as measured by $AUC_{(0–24)}$) in subjects with hepatic impairment (Child-Pugh class A, B or C) compared with healthy subjects. The increase in fluticasone furoate systemic exposure (fluticasone furoate/vilanterol 200/25 µg) in subjects with moderate hepatic impairment (Child-Pugh class B) was associated with an average 34 % reduction in serum cortisol compared with healthy subjects. In subjects with severe hepatic impairment (Child-Pugh class C) that received a lower dose of 100/12,5 µg there was no reduction in serum cortisol. For patients with moderate (Child-Pugh class B) or severe (Child-Pugh class C) hepatic impairment the maximum dose is 100/25 µg (see section 4.2). Following repeat dosing of fluticasone furoate/vilanterol for 7 days, there was no significant increase in systemic exposure to vilanterol (C_{max} and AUC) in subjects with mild, moderate, or severe hepatic impairment (Child-Pugh class A, B or C).

There were no clinically relevant effects of the fluticasone furoate/vilanterol combination on beta-adrenergic systemic effects (heart rate or serum potassium) in subjects with mild or moderate hepatic impairment (vilanterol, 25 µg) or with severe hepatic impairment (vilanterol, 12,5 µg) compared with healthy subjects.

6. PHARMACEUTICAL PARTICULARS:

6.1 List of excipients:

Lactose monohydrate (which contains milk protein) and magnesium stearate.

6.2 Incompatibilities:

Not applicable.

6.3 Shelf life:

24 months.

6.4 Special precautions for storage:

Store at or below 25 °C.

Following removal from the tray, the product may be stored for a maximum period of 6 weeks when stored at or below 25 °C. Write the date the inhaler should be discarded on the label in the space provided. The date should be added as soon as the inhaler has been removed from the tray.

If stored in the refrigerator, allow the inhaler to return to room temperature for at least an hour before use.

Keep out of reach of children.

6.5 Nature and contents of container:

Each Ellipta inhaler is packed into a carton.

The Ellipta inhaler is available in a pack size that delivers 30 inhalations. The blister strip consists of a formed silver coloured base foil laminate, sealed with a peelable lid foil laminate. Each blister strip contains 31 (30 dose) regularly distributed blisters. Each strip contains one empty blister which allows for correct location of the strip and test actuation of the inhaler.

6.6 Special precautions for disposal and other handling:

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

8. REGISTRATION NUMBERS:

RELVAR ELLIPTA 92/22 µg: 48/21.5.1/0249

RELVAR ELLIPTA 184/22 µg: 48/21.5.1/0250

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION:

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