ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.

1. NAME OF THE MEDICINAL PRODUCT

Rolufta Ellipta 55 micrograms inhalation powder, pre-dispensed

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each single inhalation provides a delivered dose (the dose leaving the mouthpiece) of 55 micrograms umeclidinium (equivalent to 65 micrograms of umeclidinium bromide). This corresponds to a pre-dispensed dose of 62.5 micrograms umeclidinium equivalent to 74.2 micrograms umeclidinium bromide.

Excipient with known effect

Each delivered dose contains approximately 12.5 mg of lactose monohydrate.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Inhalation powder, pre-dispensed (inhalation powder)

White powder in a grey inhaler (Ellipta) with a light green mouthpiece cover and a dose counter.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Rolufta Ellipta is indicated as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).

4.2 Posology and method of administration

Posology

The recommended dose is one inhalation once daily.

It should be administered each day at the same time of the day to maintain bronchodilation. The maximum dose is one inhalation once daily. If a dose is missed the next dose should be inhaled at the usual time the next day.

Special populations

Elderly

No dose adjustment is required in patients 65 years of age or older (see section 5.2).

Renal impairment

No dose adjustment is required in patients with renal impairment (see section 5.2).

Hepatic impairment

No dose adjustment is required in patients with mild or moderate hepatic impairment. Umeclidinium has not been studied in patients with severe hepatic impairment and should be used with caution (see section 5.2).

Paediatric population

There is no relevant use of umeclidinium in the paediatric population (under 18 years of age) for the indication of COPD.

Method of administration

For inhalation use only.

The following instructions for the 30-dose inhaler (30-day supply) also apply to the 7-dose inhaler (7-day supply).

The inhaler is packaged in a tray containing a desiccant sachet, to reduce moisture. The desiccant sachet should be thrown away and it should not be opened, eaten or inhaled.

The patient should be advised to not open the tray until they are ready to inhale a dose.

If the inhaler cover is opened and closed without inhaling the medicinal product, the dose will be lost. The lost dose will be securely held inside the inhaler, but it will no longer be available to be inhaled.

It is not possible to accidentally take extra medicinal product or a double dose in one inhalation.

Instructions for use

a) Prepare a dose

Open the cover when ready to inhale a dose. The inhaler should not be shaken.

Slide the cover down until a "click" is heard. The medicinal product is now ready to be inhaled.

The dose counter counts down by 1 to confirm. If the dose counter does not count down as the "click" is heard, the inhaler will not deliver a dose and should be taken back to a pharmacist for advice.

b) How to inhale the medicinal product

The inhaler should be held away from the mouth breathing out as far as is comfortable. But not breathing out into the inhaler.

The mouthpiece should be placed between the lips and the lips should then be closed firmly around it. The air vents should not be blocked with fingers during use.

- Inhale with one long, steady, deep breath in. This breath should be held in for as long as possible (at least 3-4 seconds).
- Remove the inhaler from the mouth.
- Breathe out slowly and gently.

The medicinal product may not be tasted or felt, even when using the inhaler correctly.

The mouthpiece of the inhaler may be cleaned using a **dry tissue before** closing the cover.

c) *Close the inhaler*

Slide the cover upwards as far as it will go, to cover the mouthpiece.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Asthma

Umeclidinium should not be used in patients with asthma since it has not been studied in this patient population.

Paradoxical bronchospasm

Administration of umeclidinium may produce paradoxical bronchospasm that may be life-threatening. If paradoxical bronchospasm occurs, treatment should be discontinued immediately and alternative therapy instituted if necessary.

Deterioration of disease

Umeclidinium is intended for the maintenance treatment of COPD. It should not be used for the relief of acute symptoms, i.e. as rescue therapy for the treatment of acute episodes of bronchospasm. Acute symptoms should be treated with an inhaled short-acting bronchodilator. Increasing use of short-acting bronchodilators to relieve symptoms indicates deterioration of control. In the event of deterioration of COPD during treatment with umeclidinium, a re-evaluation of the patient and of the COPD treatment regimen should be undertaken.

Cardiovascular effects

Cardiovascular effects, such as cardiac arrhythmias e.g. atrial fibrillation and tachycardia, may be seen after the administration of muscarinic receptor antagonists including umeclidinium (see section 4.8). Patients with clinically significant uncontrolled cardiovascular disease were excluded from clinical studies. Therefore, umeclidinium should be used with caution in patients with severe cardiovascular disorders, particularly cardiac arrhythmias.

Antimuscarinic activity

Due to its antimuscarinic activity, umeclidinium should be used with caution in patients with urinary retention or with narrow-angle glaucoma.

Excipients

This medicinal product contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not use this medicinal product.

4.5 Interaction with other medicinal products and other forms of interaction

Clinically significant interactions mediated by umeclidinium at clinical doses are considered unlikely due to the low plasma concentrations achieved after inhaled dosing.

Other antimuscarinics

Co-administration of umeclidinium with other long acting muscarinic antagonists or medicinal products containing this active substance has not been studied and is not recommended as it may potentiate known inhaled muscarinic antagonist adverse reactions.

Metabolic and transporter based interactions

Umeclidinium is a substrate of cytochrome P450 2D6 (CYP2D6). The steady-state pharmacokinetics of umeclidinium were assessed in healthy volunteers lacking CYP2D6 (poor metabolisers). No effect on umeclidinium AUC or C_{max} was observed at a dose 4-fold higher than the therapeutic dose. An approximately 1.3-fold increase in umeclidinium AUC was observed at an 8-fold higher dose with no effect on umeclidinium C_{max}. Based on the magnitude of these changes, no clinically relevant interaction is expected when umeclidinium is co-administered with CYP2D6 inhibitors or when administered to subjects genetically deficient in CYP2D6 activity (poor metabolisers).

Umeclidinium is a substrate of P-glycoprotein (P-gp) transporter. The effect of the moderate P-gp inhibitor verapamil (240 mg once daily) on the steady-state pharmacokinetics of umeclidinium was assessed in healthy volunteers. No effect of verapamil was observed on umeclidinium C_{max}. An approximately 1.4-fold increase in umeclidinium AUC was observed. Based on the magnitude of these changes, no clinically relevant interaction is expected when umeclidinium is co-administered with P-gp inhibitors.

Other medicinal products for COPD

Although no formal *in vivo* interaction studies have been performed, inhaled umeclidinium has been used concomitantly with other COPD medicinal products including short and long acting sympathomimetic bronchodilators and inhaled corticosteroids without clinical evidence of interactions.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no or limited amount of data from the use of umeclidinium in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3).

Umeclidinium should be used during pregnancy only if the expected benefit to the mother justifies the potential risk to the foetus.

Breast-feeding

It is unknown whether umeclidinium is excreted in human milk. A risk to breastfed newborns/infants cannot be excluded.

A decision must be made whether to discontinue breast-feeding or to discontinue Rolufta Ellipta therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

Fertility

There are no data on the effects of umeclidinium on human fertility. Animal studies indicate no effects of umeclidinium on fertility.

4.7 Effects on ability to drive and use machines

Umeclidinium has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Summary of the safety profile

The most frequently reported adverse reactions are nasopharyngitis (6%) and upper respiratory tract infection (5%).

Tabulated list of adverse reactions

The safety profile of umeclidinium was evaluated in patients with COPD who received doses of 55 micrograms or greater for up to one year. This includes patients who received the recommended dose of 55 micrograms once daily.

The frequencies assigned to the adverse reactions identified in the table below include crude incidence rates observed from efficacy studies, the long-term safety study (which involved patients who received umeclidinium), post-marketing studies and spontaneous reporting.

The frequency of adverse reactions is defined using the following convention: 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) and not known (cannot be estimated from available data).

System Organ Class	Adverse reactions	Frequency
Infections and infestations	Nasopharyngitis Upper respiratory tract infection Urinary tract infection Sinusitis Pharyngitis	Common Common Common Common Uncommon
Immune system disorders	Hypersensitivity reactions including: Rash, urticaria and pruritus Anaphylaxis	 Uncommon Rare
Nervous system disorders	Headache Dysgeusia Dizziness	Common Uncommon Not known
Eye disorders	Eye pain Glaucoma Vision blurred Intraocular pressure increased	Rare Not known Not known Not known
Cardiac disorders	Tachycardia Atrial fibrillation Rhythm idioventricular Supraventricular tachycardia Supraventricular extrasystoles	Common Uncommon Uncommon Uncommon Uncommon
Respiratory, thoracic and mediastinal disorders	Cough Oropharyngeal pain Dysphonia	Common Common Uncommon
Gastrointestinal disorders	Constipation Dry mouth	Common Uncommon
Renal and urinary disorders	Urinary retention Dysuria	Not known Not known

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

An overdose of umeclidinium will likely produce signs and symptoms consistent with the known inhaled muscarinic antagonist adverse reactions (e.g. dry mouth, visual accommodation disturbances and tachycardia).

If overdose occurs, the patient should be treated supportively with appropriate monitoring as necessary.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drugs for obstructive airway diseases, anticholinergics, ATC code: R03BB07

Mechanism of action

Umeclidinium is a long acting muscarinic receptor antagonist (also referred to as an anticholinergic). It is a quinuclidine derivative that is a muscarinic receptor antagonist with activity across multiple muscarinic cholinergic receptor subtypes. Umeclidinium exerts its bronchodilatory activity by competitively inhibiting the binding of acetylcholine with muscarinic cholinergic receptors on airway smooth muscle. It demonstrates slow reversibility at the human M3 muscarinic receptor subtype *in vitro* and a long duration of action *in vivo* when administered directly to the lungs in pre-clinical models.

Pharmacodynamic effects

In a Phase III, 6-month study (DB2113373) umeclidinium provided a clinically meaningful improvement over placebo in lung function (as measured by forced expiratory volume in 1 second [FEV_1]) over 24 hours following once daily administration, which was evident at 30 minutes following administration of the first dose (improvement over placebo by 102 mL, $p<0.001^*$). The mean peak improvements in FEV_1 within the first 6 hours following dosing relative to placebo were 130 mL ($p<0.001^*$) at week 24. There was no evidence for tachyphylaxis in the effect of umeclidinium over time.

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*A step-down statistical testing procedure was used in this study and this comparison was below a comparison that did not achieve statistical significance. Therefore, statistical significance on this comparison cannot be inferred.

Cardiac electrophysiology
The effect of umeclidinium 500 micrograms (pre-dispensed) on the QT interval was evaluated in a placebo- and moxifloxacin-controlled QT trial of 103 healthy volunteers. Following repeat doses of umeclidinium 500 micrograms once daily for 10 days, no clinically relevant effect on prolongation of QT interval (corrected using the Fridericia method) or effects on heart rate were observed.

Clinical efficacy and safety

The clinical efficacy of umeclidinium administered once daily was evaluated in 904 adult patients who received umeclidinium or placebo from two pivotal Phase III clinical studies with a clinical diagnosis of COPD; a 12-week study (AC4115408) and a 24-week study (DB2113373).

Pivotal efficacy studies:

Effects on lung function
In both of the pivotal 12-week and 24-week studies, umeclidinium demonstrated statistically significant and clinically meaningful improvements in lung function (as defined by change from baseline trough FEV_1 at week 12 and week 24 respectively, which was the primary efficacy endpoint in each study) compared with placebo (see *Table 1*). The bronchodilatory effects with umeclidinium compared with placebo were evident after the first day of treatment in both studies and were maintained over the 12-week and 24-week treatment periods.

There was no attenuation of the bronchodilator effect over time.

Table 1: Trough FEV_1 (mL) at week 12 and week 24 (primary endpoint)

Treatment with umeclidinium 55 mcg	**12-week study Treatment difference[1] 95% Confidence interval p-value**	**24-week study Treatment difference[1] 95% Confidence interval p-value**
Versus Placebo	127 (52, 202) <0.001	115 (76, 155) <0.001

mcg = micrograms
[1] least squares mean (95% confidence interval)

Umeclidinium demonstrated a statistically significant greater improvement from baseline in weighted mean FEV_1 over 0-6 hours post-dose at week 12 compared with placebo (166 mL, p<0.001) in the 12-Week pivotal study. Umeclidinium demonstrated a greater improvement from baseline in weighted mean FEV_1 over 0-6 hours post-dose at week 24 compared with placebo (150 mL, p<0.001[*]) in the 24-week pivotal study.

Symptomatic outcomes

Breathlessness:
In the 12-week study, a statistically significant improvement compared with placebo in the TDI focal score at week 12 was not demonstrated for umeclidinium (1.0 units, p=0.05). A statistically significant improvement compared with placebo in the TDI focal score at week 24 was demonstrated for umeclidinium (1.0 units, p<0.001) in the 24-week study.

[*] A step-down statistical testing procedure was used in this study and this comparison was below a comparison that did not achieve statistical significance. Therefore, statistical significance on this comparison cannot be inferred.

The proportion of patients who responded with at least the minimum clinically important difference (MCID) of 1 unit TDI focal score at week 12 was greater for umeclidinium (38%) compared with placebo (15%) in the 12-week study. Similarly, a greater proportion of patients achieved ≥1 unit TDI focal score for umeclidinium (53%) compared with placebo (41%) at week 24 in the 24-week study.

Health-related quality of life:
Umeclidinium also demonstrated a statistically significant improvement in health-related quality of life measured using the St. George's Respiratory Questionnaire (SGRQ) as indicated by a reduction in SGRQ total score at week 12 compared with placebo (-7.90 units, p<0.001) in the 12-week study. A greater improvement compared with placebo in the change from baseline in SGRQ total score at week 24 was demonstrated for umeclidinium (-4.69 units, p<0.001*) in the 24-week study.

The proportion of patients who responded with at least the MCID in SGRQ score (defined as a decrease of 4 units from baseline) at week 12 was greater for umeclidinium 55 micrograms (44%) compared with placebo (26%) in the 12-week study. Similarly, a greater proportion of patients achieved at least the MCID for umeclidinium at week 24 (44%) compared with placebo (34%) in the 24-week study.

COPD exacerbations
In the 24-week placebo-controlled study in patients with symptomatic COPD, umeclidinium reduced the risk of a moderate/severe COPD exacerbation by 40% compared with placebo (analysis of time to first exacerbation; Hazard Ratio 0.6; 95% CI: 0.4, 1.0, p=0.035*). The probability of having an exacerbation in patients receiving umeclidinium at Week 24 was 8.9% compared with 13.7% for placebo. These studies were not specifically designed to evaluate the effect of treatments on COPD exacerbations and patients were withdrawn from the study if an exacerbation occurred.

Use of rescue medicinal product
In the 12-week study, umeclidinium statistically significantly reduced the use of rescue medication with salbutamol compared with placebo (on average a reduction of 0.7 puffs per day over weeks 1-12, p=0.025) and demonstrated a higher percentage of days when no rescue medication was needed (on average 46.3%) compared with placebo (on average 35.2%; no formal statistical analysis was performed on this endpoint). In the 24-week study treatment with umeclidinium, the mean (SD) change from baseline in the number of puffs of rescue salbutamol over the 24-week treatment period was -1.4 (0.20) for placebo and -1.7 (0.16) for umeclidinium (Difference = -0.3; 95% CI: -0.8, 0.2, p=0.276). Patients receiving umeclidinium had a higher percentage of days when no rescue medication was needed (on average 31.1%) compared with placebo (on average 21.7%). No formal statistical testing was performed on this endpoint.

Supporting efficacy studies
In a randomised, double-blind, 52-week study (CTT116855, IMPACT) of 10,355 adult patients with symptomatic COPD and a history of 1 or more moderate or severe exacerbations within the prior 12 months, treatment with fluticasone furoate/umeclidinium/vilanterol (FF/UMEC/VI 92/55/22 micrograms) once daily as a single inhaler was compared with fluticasone furoate/vilanterol (FF/VI 92/22 micrograms) once daily as a single inhaler. The primary endpoint was annual rate of on-treatment moderate and severe exacerbations in subjects treated with FF/UMC/VI compared with FF/VI. The mean annual rate of exacerbations was 0.91 and 1.07 for FF/UMEC/VI and FF/VI respectively (Rate Ratio: 0.85; 95% CI: 0.80, 0.90; p<0.001).

At week 52, a statistically significant improvement in the least-squares (LS) mean change from baseline in trough FEV1 was observed for FF/UMEC/VI compared with FF/VI (mean change: +94 mL vs. -3 mL; treatment difference: 97 mL; 95% CI: 85, 109; p<0.001).

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*A step-down statistical testing procedure was used in this study and this comparison was below a comparison that did not achieve statistical significance. Therefore, statistical significance on this comparison cannot be inferred.

In two 12-week, placebo controlled studies (200109 and 200110), the addition of umeclidinium to fluticasone furoate/vilanterol (FF/VI) (92/22 micrograms) once daily in adult patients with a clinical diagnosis of COPD, resulted in statistically significant and clinically meaningful improvements in the primary endpoint of trough FEV_1 at Day 85 compared to placebo plus FF/VI (124 mL 95% CI: 93, 154; p<0.001 and 122 mL 95% CI: 91, 152; p<0.001).

Improvements in lung function were supported with reductions in use of salbutamol over weeks 1-12 (-0.4 puffs per day (95% CI: -0.7, -0.2; p<0.001) and -0.3 puffs per day (95% CI: -0.5, -0.1; p=0.003) compared to placebo plus FF/VI but improvements in SGRQ at week 12 were not statistically significant (200109) or clinically relevant (200109 and 200110). The short duration of these two studies and limited number of exacerbation events, preclude any conclusion regarding additional effect of umeclidinium on COPD exacerbation rate.

No new adverse drug reactions were identified with the addition of umeclidinium to FF/VI in these studies.

Paediatric population

The European Medicines Agency has waived the obligation to submit the results of studies with Rolufta Ellipta in all subsets of the paediatric population in COPD (see section 4.2 for information on paediatric use).

5.2 Pharmacokinetic properties

Absorption

Following inhaled administration of umeclidinium in healthy volunteers, C_{max} occurred at 5 to 15 minutes. The absolute bioavailability of inhaled umeclidinium was on average 13% of the dose, with negligible contribution from oral absorption. Following repeat dosing of inhaled umeclidinium, steady state was achieved within 7 to 10 days with 1.5 to 1.8-fold accumulation.

Distribution

Following intravenous administration to healthy subjects, the mean volume of distribution was 86 litres. *In vitro* plasma protein binding in human plasma was on average 89%.

Biotransformation

In vitro studies showed that umeclidinium is principally metabolised by cytochrome P450 2D6 (CYP2D6) and is a substrate for the P-glycoprotein (P-gp) transporter. The primary metabolic routes for umeclidinium are oxidative (hydroxylation, O-dealkylation) followed by conjugation (glucuronidation, etc), resulting in a range of metabolites with either reduced pharmacological activity or for which the pharmacological activity has not been established. Systemic exposure to the metabolites is low.

Elimination

Plasma clearance following intravenous administration was 151 litres/hour. Following intravenous administration, approximately 58% of the administered radiolabelled dose (or 73% of the recovered radioactivity) was excreted in faeces by 192 hours post-dose. Urinary elimination accounted for 22% of the administered radiolabelled dose by 168 hours (27% of recovered radioactivity). The excretion of the material in the faeces following intravenous dosing indicated secretion into the bile. Following oral administration to healthy male subjects, total radioactivity was excreted primarily in faeces (92% of the administered radiolabelled dose or 99% of the recovered radioactivity) by 168 hours post-dose. Less than 1% of the orally administered dose (1% of recovered radioactivity) was excreted in urine, suggesting negligible absorption following oral administration. Umeclidinium plasma elimination

half-life following inhaled dosing for 10 days averaged 19 hours, with 3% to 4% active substance excreted unchanged in urine at steady-state.

Special populations

Elderly
A population pharmacokinetic analysis showed that pharmacokinetics of umeclidinium are similar between COPD patients 65 years and older and those younger than 65 years of age.

Renal impairment
Subjects with severe renal impairment (creatinine clearance <30 mL/min) showed no evidence of an increase in systemic exposure to umeclidinium (C_{max} and AUC), and no evidence of altered protein binding between subjects with severe renal impairment and healthy volunteers.

Hepatic impairment
Subjects with moderate hepatic impairment (Child-Pugh Class B) showed no evidence of an increase in systemic exposure to umeclidinium (C_{max} and AUC), and no evidence of altered protein binding between subjects with moderate hepatic impairment and healthy volunteers. Umeclidinium has not been evaluated in subjects with severe hepatic impairment.

Other special populations
A population pharmacokinetic analysis showed that no dose adjustment is required for umeclidinium based on the effect of age, race, gender, inhaled corticosteroid use or weight. A study in CYP2D6 poor metabolisers showed no evidence of a clinically significant effect of CYP2D6 genetic polymorphism on systemic exposure to umeclidinium.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity and carcinogenic potential. In non-clinical studies with umeclidinium, findings were those typically associated with the primary pharmacology of muscarinic receptor antagonists and/or local irritancy.

Toxicity to reproduction

Umeclidinium was not teratogenic in rats or rabbits. In a pre- and post-natal study, subcutaneous administration of umeclidinium to rats resulted in lower maternal body weight gain and food consumption and slightly decreased pre-weaning pup body weights in dams given 180 micrograms/kg/day dose (approximately 80-times the human clinical exposure of umeclidinium 55 micrograms, based on AUC).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.
In-use shelf life after opening the tray: 6 weeks.

6.4 Special precautions for storage

Do not store above 30°C. If stored in the refrigerator, allow the inhaler to return to room temperature for at least an hour before use.

Keep the inhaler inside the sealed tray in order to protect from moisture and only remove immediately before first use.

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.

6.5 Nature and contents of container

The Ellipta inhaler consists of a grey body, a light green mouthpiece cover and a dose counter, packed into a foil laminate tray containing a silica gel desiccant sachet. The tray is sealed with a peelable foil lid.

The inhaler is a multi-component device composed of polypropylene, high density polyethylene, polyoxymethylene, polybutylene terephthalate, acrylonitrile butadiene styrene, polycarbonate and stainless steel.

The inhaler contains one aluminium foil laminate blister of 7 or 30-doses (7 or 30 day supply).

Pack sizes of 1 inhaler with 7 or 30-doses.
Multipacks containing 90 (3 inhalers of 30) doses.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

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

7. MARKETING AUTHORISATION HOLDER

GlaxoSmithKline Trading Services Limited
12 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

8. MARKETING AUTHORISATION NUMBER(S)

EU/1/17/1174/001
EU/1/17/1174/002
EU/1/17/1174/003

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th March 2017
Date of latest renewal: 07th January 2022

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 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 RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Glaxo Wellcome Production
Zone Industrielle No.2
23 Rue Lavoisier
27000 Evreux
France

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Medicinal product subject to medical prescription.

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.

• Obligation to conduct post-authorisation measures

The MAH shall complete, within the stated timeframe, the below measure:

Description	Due date
Submission of the final clinical study report on a Post-Authorisation Safety (PAS) Observational Cohort Study to Quantify the Incidence and Comparative Safety of Selected Cardiovascular and Cerebrovascular Events in COPD Patients Using Inhaled UMEC/VI Combination or Inhaled UMEC versus Tiotropium (Study 201038), according to a protocol agreed by the PRAC.	By Q3 2024

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON (SINGLE PACKS)

1. NAME OF THE MEDICINAL PRODUCT

Rolufta Ellipta 55 micrograms inhalation powder, pre-dispensed
umeclidinium

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each delivered dose contains 55 micrograms umeclidinium (equivalent to 65 micrograms of umeclidinium bromide).

3. LIST OF EXCIPIENTS

Excipients: lactose monohydrate and magnesium stearate.
See package leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Inhalation powder, pre-dispensed
7 doses
30 doses
1 inhaler of 7 doses
1 inhaler of 30 doses

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Once daily.
Read the package leaflet before use.
Inhalation use.
Do not shake.

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

Do not swallow the desiccant.

8. EXPIRY DATE

EXP

In-use shelf life: 6 weeks.

9. SPECIAL STORAGE CONDITIONS

Do not store above 30°C.
Store in the original package in order to protect from moisture.

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

GlaxoSmithKline Trading Services Limited
12 Riverwalk
Citywest Business Campus
Dublin 24
Ireland
GlaxoSmithKline Trading Service Limited logo

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/17/1174/001
EU/1/17/1174/002

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

rolufta ellipta

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 OUTER PACKAGING

OUTER CARTON FOR MULTIPACK (WITH BLUE BOX)

1. NAME OF THE MEDICINAL PRODUCT

Rolufta Ellipta 55 micrograms inhalation powder, pre-dispensed
umeclidinium

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each delivered dose contains 55 micrograms umeclidinium (equivalent to 65 micrograms of umeclidinium bromide).

3. LIST OF EXCIPIENTS

Excipients: lactose monohydrate and magnesium stearate.
See package leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Inhalation powder, pre-dispensed
Multipack: 90 (3 inhalers of 30) doses

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Once daily.
Read the package leaflet before use.
Inhalation use.
Do not shake.

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

Do not swallow the desiccant.

8. EXPIRY DATE

EXP
In-use shelf life: 6 weeks.

9. SPECIAL STORAGE CONDITIONS

Do not store above 30°C.
Store in the original package in order to protect from moisture.

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

GlaxoSmithKline Trading Services Limited
12 Riverwalk
Citywest Business Campus
Dublin 24
Ireland
GlaxoSmithKline Trading Service Limited logo

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/17/1174/003

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

rolufta ellipta

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 OUTER PACKAGING

INTERMEDIATE CARTON OF MULTIPACK (WITHOUT BLUE BOX)

1. NAME OF THE MEDICINAL PRODUCT

Rolufta Ellipta 55 micrograms inhalation powder, pre-dispensed
umeclidinium

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each delivered dose contains 55 micrograms umeclidinium (equivalent to 65 micrograms of umeclidinium bromide).

3. LIST OF EXCIPIENTS

Excipients: lactose monohydrate and magnesium stearate.
See package leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Inhalation powder, pre-dispensed
1 inhaler of 30 doses
Component of a multipack can't be sold separately.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Once daily.
Read the package leaflet before use.
Inhalation use.
Do not shake.

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

Do not swallow the desiccant.

8. EXPIRY DATE

EXP
In-use shelf life: 6 weeks.

9. SPECIAL STORAGE CONDITIONS

Do not store above 30°C.
Store in the original package in order to protect from moisture.

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

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14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

rolufta ellipta

17. UNIQUE IDENTIFIER – 2D BARCODE

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

FOIL LAMINATE TRAY LID

1. NAME OF THE MEDICINAL PRODUCT

Rolufta Ellipta 55 mcg inhalation powder
umeclidinium

2. NAME OF THE MARKETING AUTHORISATION HOLDER

GlaxoSmithKline Trading Services Limited logo

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER

Do not open until ready to inhale.
In-use shelf life: 6 weeks.
7 doses
30 doses

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

INHALER LABEL

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Rolufta Ellipta 55 mcg inhalation powder
umeclidinium
Inhalation use

2. METHOD OF ADMINISTRATION

3. EXPIRY DATE

EXP
In-use shelf life: 6 weeks.
Discard by:

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

7 doses
30 doses

6. OTHER

B. PACKAGE LEAFLET

Package leaflet: Information for the patient

Rolufta Ellipta 55 micrograms inhalation powder, pre-dispensed
umeclidinium

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Rolufta Ellipta is and what it is used for

What Rolufta Ellipta is

Rolufta Ellipta contains the active substance umeclidinium (as bromide), which belongs to a group of medicines called bronchodilators.

What Rolufta Ellipta is used for

This medicine is used to treat chronic obstructive pulmonary disease (**COPD**) in adults. COPD is a long-term condition in which the airways and air-sacs in the lungs gradually become blocked or damaged, leading to breathing difficulties that slowly get worse. Difficulties in breathing is added to by tightening of the muscles around the airways, which narrows the airways and so restricts the flow of air.

This medicine blocks the tightening of these muscles, making it easier for air to get in and out of the lungs. When used regularly, it can help control your breathing difficulties and reduce the effects of COPD on your everyday life.

Rolufta Ellipta should not be used to relieve a sudden attack of breathlessness or wheezing.
If you get this sort of attack you must use a quick-acting reliever inhaler (such as salbutamol). If you do not have a quick-acting inhaler contact your doctor.

2. What you need to know before you use Rolufta Ellipta

Do not use Rolufta Ellipta:
- if you are **allergic** to umeclidinium or any of the other ingredients of this medicine (listed in section 6).

If you think the above applies to you, **do not use** this medicine until you have checked with your doctor.

Warnings and precautions
Talk to your doctor before using Rolufta Ellipta:
- if you have **asthma** (Do not use Rolufta Ellipta to treat asthma)
- if you have **heart problems**
- if you have an eye problem called **narrow-angle glaucoma**
- if you have an **enlarged prostate**, **difficulty passing urine** or a **blockage in your bladder**
- if you have **severe liver problems**

Check with your doctor if you think any of these may apply to you.

Immediate breathing difficulties
If you get tightness of the chest, coughing, wheezing or breathlessness immediately after using your Rolufta Ellipta inhaler:

stop using this medicine and seek medical help immediately, as you may have a serious condition called paradoxical bronchospasm.

Eye problems during treatment with Rolufta Ellipta
If you get eye pain or discomfort, temporary blurring of vision, visual halos or coloured images in association with red eyes during treatment with Rolufta Ellipta:

stop using this medicine and seek medical help immediately, these may be signs of an acute attack of narrow-angle glaucoma.

Children and adolescents
Do not give this medicine to **children or adolescents below the age of 18 years**.

Other medicines and Rolufta Ellipta
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. If you are not sure what your medicine contains talk to your doctor or pharmacist.

In particular, tell your doctor or pharmacist if you are taking other long-acting medicines similar to this medicine for breathing problems, e.g. tiotropium. Do not use Rolufta Ellipta together with these other medicines.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, **ask your doctor for advice** before using this medicine. Do not use this medicine if you are pregnant unless your doctor tells you so.

It is not known whether the ingredients of Rolufta Ellipta can pass into breast milk. **If you are breast-feeding, you must check with your doctor** before you use Rolufta Ellipta. Do not use this medicine if you are breast-feeding unless your doctor tells you that you can.

Driving and using machines
It is unlikely that this medicine will affect your ability to drive or use machines.

Rolufta Ellipta contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before using this medicine.

3. How to use Rolufta Ellipta

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

The recommended dose is one inhalation every day at the same time of day. You only need to inhale once a day because the effect of this medicine lasts for 24 hours.

Do not use more than your doctor tells you to use.

Use Rolufta Ellipta regularly
It is very important that you use Rolufta Ellipta every day, as instructed by your doctor. This will help to keep you free of symptoms throughout the day and night.

Do **not** use this medicine to relieve a **sudden attack of breathlessness or wheezing**. If you get this sort of attack you must use a quick-acting reliever inhaler (such as salbutamol).

How to use the inhaler
See 'Step-by-step instructions for use' at the end of this leaflet for full information.

Rolufta Ellipta is for inhalation use. To use Rolufta Ellipta, you breathe it into your lungs through your mouth using the Ellipta inhaler.

If your symptoms do not improve
If your COPD symptoms (breathlessness, wheezing, cough) do not improve or get worse, or if you are using your quick-acting inhaler more often:
contact your doctor as soon as possible.

If you use more Rolufta Ellipta than you should
If you accidentally use too much of this medicine, **contact your doctor or pharmacist for advice immediately** as you may need medical attention. If possible, show them the inhaler, the package or this leaflet. You may notice that your heart is beating faster than usual, you have visual disturbances or have a dry mouth.

If you forget to use Rolufta Ellipta
Do not inhale a double dose to make up for a forgotten dose. Just inhale your next dose at the usual time.
If you become wheezy or breathless, use your quick-acting inhaler (such as salbutamol), then seek medical advice.

If you stop using Rolufta Ellipta
Use this medicine for as long as your doctor recommends. It will only be effective as long as you are using it. Do not stop unless your doctor advises you to, even if you feel better, as your symptoms may get worse.

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

4. Possible side effects

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

Allergic reactions

If you have any of the following symptoms after taking Rolufta Ellipta, **stop using this medicine and tell your doctor immediately:**

Uncommon (may affect **up to 1 in 100** people):
- itching
- skin rash (*hives*) or redness.

Rare (may affect **up to 1 in 1 000** people):
- wheezing, coughing or having difficulty in breathing
- suddenly feeling weak or light headed (which may lead to collapse or loss of consciousness).

Other side effects

Common (may affect **up to 1 in 10** people):
- faster heart beat
- painful and frequent urination (may be signs of a urinary tract infection)
- common cold
- infection of nose and throat
- cough
- feeling of pressure or pain in the cheeks and forehead (may be signs of inflammation of the sinuses called sinusitis)
- headache
- constipation
- mouth and throat pain.

Uncommon (may affect **up to 1 in 100** people)
- irregular heart beat
- sore throat
- dry mouth
- taste disturbance
- hoarseness.

Rare (may affect **up to 1 in 1 000** people)
- eye pain.

Not known (frequency cannot be estimated from the available data)
- decrease in vision or pain in your eyes due to high pressure (possible signs of glaucoma)
- blurred vision
- increase of the measured eye pressure
- difficulty and pain when passing urine – these may be signs of a bladder obstruction or urinary retention
- dizziness.

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 Rolufta Ellipta

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, tray and inhaler after 'EXP'. The expiry date refers to the last day of that month.

Keep the inhaler inside the sealed tray in order to protect from moisture and only remove immediately before first use. Once the tray is opened, the inhaler can be used for up to 6 weeks, starting from the date of opening the tray. Write the date the inhaler should be thrown away on the label in the space provided. The date should be added as soon as the inhaler has been removed from the tray.

Do not store above 30°C.

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

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 Rolufta Ellipta contains
The active substance is umeclidinium (as bromide).

Each single inhalation provides a delivered dose (the dose leaving the mouthpiece) of 55 micrograms umeclidinium (equivalent to 65 micrograms of umeclidinium bromide).

The other ingredients are lactose monohydrate (see section 2 under 'Rolufta Ellipta contains lactose') and magnesium stearate.

What Rolufta Ellipta looks like and contents of the pack
Rolufta Ellipta is an inhalation powder, pre-dispensed.
The Ellipta inhaler consists of a grey plastic body, a light green mouthpiece cover and a dose counter. It is packaged in a foil laminate tray with a peelable foil lid. The tray contains a desiccant packet, to reduce moisture in the packaging.

The active substance is present as a white powder in a blister inside the inhaler. Rolufta Ellipta is available in packs of 1 inhaler containing either 7 or 30 doses and in multipacks containing 90 (3 inhalers of 30) doses. Not all pack sizes may be marketed.

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This leaflet was last revised in

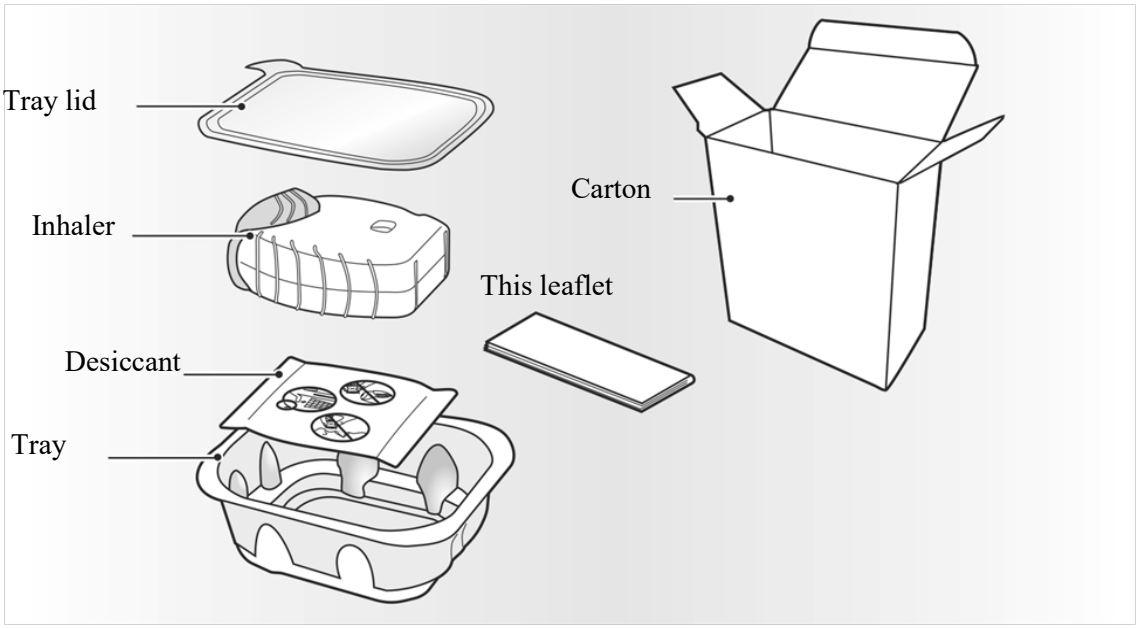
Other sources of information

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

Step-by-step instructions for use

What is the Ellipta inhaler?
The first time you use Rolufta Ellipta you do not need to check that the inhaler is working properly; it contains previously measured doses and is ready to use straight away.

Your Rolufta Ellipta inhaler carton contains



The inhaler is packaged in a tray. **Do not open the tray until you are ready to start using your new inhaler.** When you are ready to use your inhaler, peel back the lid to open the tray. The tray contains a **desiccant** sachet, to reduce moisture. Throw this desiccant sachet away – **do not** open, eat or inhale it.

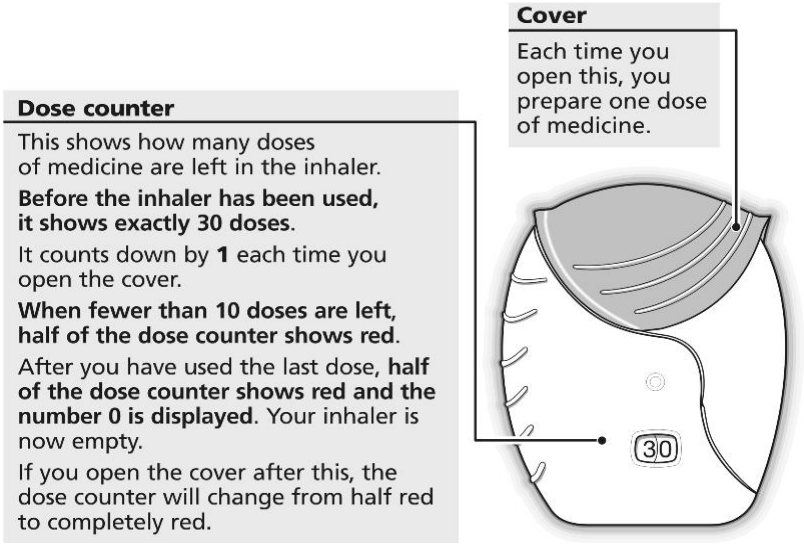
When you take the inhaler out of its tray, it will be in the 'closed' position. **Do not open the inhaler until you are ready to inhale a dose of medicine**. When the tray is opened, write the "Discard by" date on the inhaler label in the space provided. The "Discard by" date is 6 weeks from the date you opened the tray. After this date the inhaler should no longer be used. The tray can be discarded after first opening.

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

The step-by-step instructions for use of the Ellipta inhaler provided below can be used for either the 30-dose inhaler (30-day supply) or the 7-dose inhaler (7-day supply).

1) Read this before you start

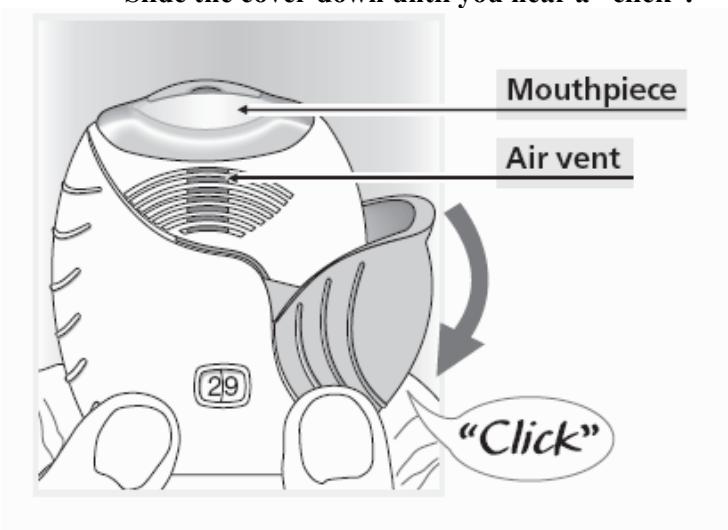
If you open and close the cover without inhaling the medicine, you will lose the dose.
The lost dose will be securely held inside the inhaler, but it will no longer be available.
It is not possible to accidentally take extra medicine or a double dose in one inhalation.



2) Prepare a dose

Wait to open the cover until you are ready to inhale your dose.
Do not shake the inhaler.

- **Slide the cover down until you hear a "click".**



Your medicine is now ready to be inhaled.

The dose counter counts down by **1** to confirm.

- **If the dose counter does not count down as you hear the "click", the inhaler will not deliver medicine**.
  Take it back to your pharmacist for advice.

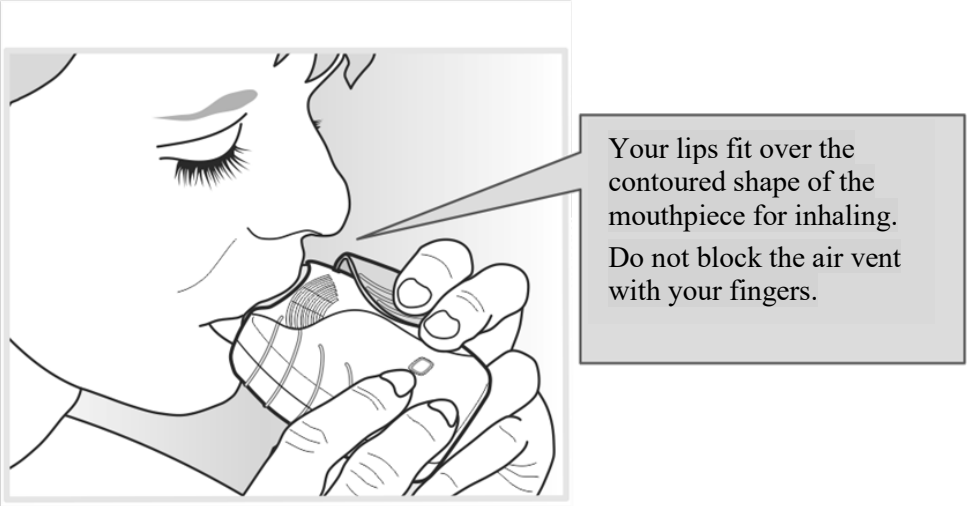
3) Inhale your medicine

- **While holding the inhaler away from your mouth, breathe out as far as is comfortable.**

Do not breathe out into the inhaler.

- **Put the mouthpiece between your lips, and close your lips firmly around it.**

Do not block the air vent with your fingers.

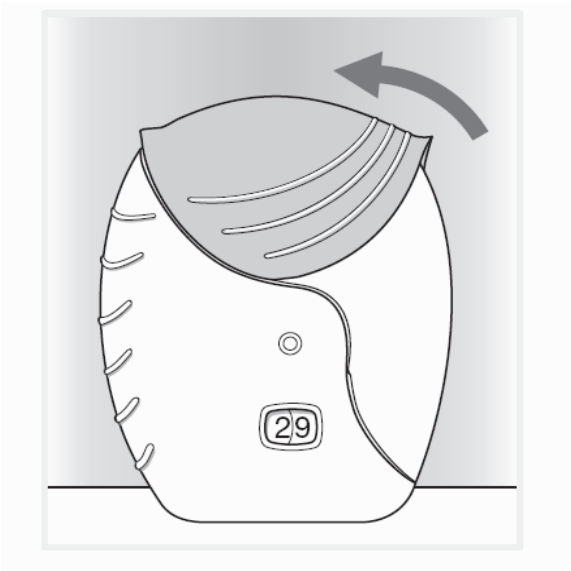


- Take one long, steady, deep breath in. Hold this breath in for as long as possible (at least 3-4 seconds).
- Remove the inhaler from your mouth.
- Breathe out slowly and gently.

You may not be able to taste or feel the medicine, even when you are using the inhaler correctly.

If you want to clean the mouthpiece, use a **dry tissue**, **before** you close the cover.

4) Close the inhaler



Slide the cover upwards as far as it will go, to cover the mouthpiece.