Product Summary for *Incruse Ellipta*

This information is provided in response to your request for information about Incruse® Ellipta® (umeclidinium inhalation powder).

SUMMARY

- Important safety information is found in the attached Prescribing Information.

DISEASE BACKGROUND

- Inhaled bronchodilators, including anticholinergics, are central to the symptom management of chronic obstructive pulmonary disease (COPD).[1] The Global Initiative for Chronic Obstructive Pulmonary Disease (GOLD) committee recommends long-acting anticholinergic as recommended first choice therapy for COPD patients with significant symptoms and a low risk of exacerbations (Group B), less symptoms and a high risk of exacerbations (Group C), and significant symptoms and a high risk of exacerbation (Group D).

DESCRIPTION

- *Incruse Ellipta* is a once-daily, anticholinergic delivered from a dry powder breath-actuated device. The dry powder inhaler contains a double-foil blister strip with each blister containing *Incruse Ellipta* 62.5 mcg.[2]

INDICATION

- *Incruse Ellipta* is an anticholinergic indicated for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema.[2]

DOSING

- *Incruse Ellipta 62.5 mcg* should be administered as 1 inhalation once daily by the orally inhaled route only.[2]
- *Incruse Ellipta* should be taken at the same time every day. Do not use *Incruse Ellipta* more than 1 time every 24 hours.

EFFICACY DATA

- The clinical development program of *Incruse Ellipta* included 2 (one 12 week trial and one 24 week trial) randomized, double-blind, placebo-controlled, parallel group trials in subjects with COPD designed to evaluate the efficacy of *Incruse Ellipta* on lung function.[2] The primary endpoint for both studies was change from baseline in trough forced expiratory volume in one second (FEV_1) on day 169 and day 85, respectively. A secondary endpoint was weighted mean (wm) FEV_1 at 0-6 hour on Day 168 and day 84, respectively.[2]
- In Trial 1 (N = 698), *Incruse Ellipta* significantly improved trough FEV_1 at day 169 by 115 mL ([95% CI 76, 155]; $P < 0.001$), and 0-6 hour wm FEV_1 at day 168 by 150 mL ([95% CI 110, 190]; $P < 0.001$) compared with placebo.[2,3]
- In Trial 2 (N = 206), *Incruse Ellipta* significantly improved trough FEV_1 at day 85 by 127 mL ([95% CI 52, 202]; $P < 0.001$) and 0-6 hour wm FEV_1 at day 84 by 166 mL ([95% CI 94, 239]; $P < 0.001$) compared to placebo.[4]
- In addition to lung function, health-related quality of life was assessed in the clinical trials of *Incruse Ellipta* using the St. George's Respiratory Questionnaire (SGRQ), a respiratory disease-specific, subject-reported instrument that measures symptoms, activities, and impact on daily life.[1]
- In Trial 1 and Trial 2, treatment with *Incruse Ellipta* resulted in statistically and clinically significant improvements in mean SGRQ total score compared to placebo at day 168 with a difference of -4.69 ([95% CI: -7.07, -2.31], $P <0.001$) and at day 84 with a difference of -7.9 ([95% CI: -12.2, -3.6], $P <0.001$).[3,4] The proportion of patients with a clinically meaningful improvement in SGRQ scores (defined as a decrease of at least 4 units from baseline) was greater for *Incruse Ellipta* (42%;172/410) compared to placebo (31%; 86/274) at day 169 in Trial 1. The proportion of patients with a clinically meaningful improvement in SGRQ scores was greater in the *Incruse Ellipta* treatment group (44%; 28/69) compared to placebo treatment group (26%; 14/54) at day 84 in Trial 2.

CONTRAINDICATIONS

- The use of *Incruse Ellipta* is contraindicated in patients with severe hypersensitivity to milk proteins or who have hypersensitivity to either umeclidinium or any of the excipients.[2]

WARNINGS AND PRECAUTIONS

- *Incruse Ellipta* should not be initiated in patients during rapidly deteriorating or potentially life-threatening episodes of COPD. *Incruse Ellipta* should not be used for the relief of acute symptoms, i.e., as rescue therapy for the treatment of acute episodes of bronchospasm.
- If paradoxical bronchospasm occurs following the dosing with *Incruse Ellipta*, treat immediately with an inhaled short-acting bronchodilator and discontinue *Incruse Ellipta* and institute alternative therapy.
- Patients with severe milk protein allergy should not use *Incruse Ellipta*. There have been reports of anaphylactic reactions in patients with severe milk protein allergy after inhalation of other powder products containing lactose.
- Use with caution in patients with narrow-angle glaucoma and urinary retention.

ADVERSE EVENTS

- The most common adverse reactions (≥1% and more common than placebo) reported with *Incruse Ellipta* (and placebo) were nasopharyngitis 8% (7%); upper respiratory tract infection 5% (4%); pharyngitis 1% (< 1%); viral upper respiratory tract infection 1% (<1%); cough 3% (2%); arthralgia 2% (1%); myalgia 1% (<1%); abdominal pain upper 1% (< 1%); toothache 1% (<1%); contusion 1% (< 1%); tachycardia 1% (<1%).[2]

This information is provided in response to your request. GSK requests that the recipient of this information only share the contents with the Pharmacy & Therapeutics (P & T) Committee members for the purposes of making evidence-based decisions regarding formulary inclusion.

REFERENCE(S)

1. Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2015. Available from http://www.goldcopd.org. Accessed January 28, 2015. *
2. GlaxoSmithKline Local Label. *

3. Donohue J, Maleki-Yazdi M, Kildride S, et al. Efficacy and safety of once-daily umeclidinium/vilanterol 62.5/25 mcg in COPD. Resp Med 2013;107(10):1538-1546. (DB2113373).http://dx.doi.org/10.1016/j.med.2013.06.001.*
4. Trivedi R, Richard N, Mehta R, et al. Umeclidinium in patients with COPD: a randomised, placebo-controlled study. Eur Respir J 2014;43:72–81. (AC4115408).*