

Umeclidinium (Incruse Ellipta) for COPD

R. CHRISTOPHER DURIGAN, PharmD, BCPS, *Thundermist Health Center, Woonsocket, Rhode Island*

VALERIE NIEDERMIER, MD, *University of Pittsburgh Medical Center St. Margaret, Pittsburgh, Pennsylvania*

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Umeclidinium inhalation powder (Incruse Ellipta) is a long-acting anticholinergic medication labeled for maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including emphysema and chronic bronchitis.¹

Drug	Dosage	Dose form	Cost*
Umeclidinium (Incruse Ellipta)	One inhalation (62.5 mcg) daily; no titration required	Inhaler preloaded with one-dose blisters of dry powder medication	\$315

*—Estimated retail price of one month's treatment based on information obtained at <http://www.goodrx.com> (accessed November 3, 2016).

SAFETY

Umeclidinium is a relatively safe medication with few systemic adverse effects. As with aclidinium (Tudorza Pressair), umeclidinium powder contains lactose and should not be used by patients with severe milk protein allergy because anaphylactic reactions have been reported. Similar to other anticholinergic medications, umeclidinium can theoretically cause paradoxical bronchospasm, urinary retention, and cardiac effects.¹ Adverse effects with umeclidinium monotherapy are similar to those of umeclidinium combined with an inhaled corticosteroid and a long-acting beta-2 adrenergic agonist.¹ Trials assessing adverse effects for umeclidinium included a relatively small number of patients (n = 576) and are therefore underpowered for rare but potentially important harms. Umeclidinium has not been studied in pregnant women, and it is unknown whether it is excreted in breast milk. It is a pregnancy risk category C.¹

TOLERABILITY

Umeclidinium is fairly well tolerated. The most common adverse effects are nasopharyngitis (8% vs. 7% with placebo), upper respiratory tract infection (5% vs. 4%),

cough (3% vs. 2%), and arthralgia (2% vs. 1%).¹ In clinical trials, the drop-out rate was 7%, compared with 4% of the placebo group in the primary efficacy trial, and was mostly related to a pulmonary disorder (3%), infection (1%), or a cardiac event (2%).² Some patients may feel that the powder has an unpleasant lactose taste.

EFFECTIVENESS

Umeclidinium is at least as effective as tiotropium (Spiriva) for the treatment of COPD symptoms in patients with moderate to severe disease. Umeclidinium improves quality of life as demonstrated by a decreased score on the St. George's Respiratory Questionnaire.³ It also improves patient-reported dyspnea as measured by the Transition Dyspnea Index.⁴ These clinically relevant symptom improvements are similar to those of tiotropium.³ Umeclidinium delays the time to first COPD exacerbation compared with placebo (hazard ratio = 0.61; 95% confidence interval, 0.41 to 0.90).³ Umeclidinium also provides improvement in trough forced expiratory volume in one second (FEV₁) from baseline when combined with an inhaled corticosteroid with or without a long-acting beta agonist.

However, studies evaluating FEV₁ changes with umeclidinium alone are lacking.^{3,5} There is no research on umeclidinium's long-term effects on frequency of exacerbations, hospitalizations, and mortality in patients with COPD, and umeclidinium has not been studied in patients with asthma.

PRICE

The average price of umeclidinium is \$315 per month. It is less expensive than other long-acting anticholinergic inhalers (e.g., tiotropium, \$360) and long-acting beta agonists (e.g., salmeterol [Serevent Diskus], \$340). However, umeclidinium may be a higher-tier medication on certain health plans (typically tier 3 or 4), resulting in a higher co-pay, and it is not covered by all insurance plans.

SIMPLICITY

The recommended dosage of umeclidinium is one 62.5-mcg inhalation daily. The administration device is preloaded with blisters of dry powder medication, requiring no user preparation. Each dose is automatically loaded when the user opens the lid until hearing a click. There is no dose adjustment required for patients with renal or hepatic impairment.

Bottom Line

Umeclidinium is an easy-to-use, once-daily, well-tolerated, and relatively low-cost anticholinergic agent for maintenance therapy

in patients with moderate to severe COPD. It is at least as effective as tiotropium and improves dyspnea, quality of life, and FEV₁, although its role among the current COPD maintenance therapies is unclear. It should be considered a first-line long-acting anticholinergic agent for moderate to severe COPD, especially for patients who cannot afford tiotropium or use it appropriately.

Address correspondence to R. Christopher Durigan, PharmD, BCPS, at rcdurigan@gmail.com. Reprints are not available from the authors.

Author disclosure: No relevant financial affiliations.

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