

# DTB CME/CPD Answers



Drug and Therapeutics Bulletin

## ▼ Olodaterol—another LABA for COPD

### Question 1

The Global Initiative for Chronic Obstructive Lung Disease (GOLD) classifies COPD severity into four grades based on a patient's postbronchodilator forced expiratory volume in 1 second (FEV<sub>1</sub>). According to the GOLD classification which one of the following FEV<sub>1</sub> ranges corresponds to severe COPD in patients with FEV<sub>1</sub>/FVC <0.7?

- a. 60–89% predicted
- b. 50–79% predicted
- c. 40–69% predicted
- d. 30–49% predicted
- e. ≤39% predicted

Answer: d. According to GOLD, severe COPD is classified as stage 3 with a postbronchodilator 30%≤FEV<sub>1</sub><50% predicted.

### Question 2

The assessment of treatments for COPD is usually based on measures of lung function, symptoms and patient-related endpoints. The St. George's Respiratory Questionnaire (SGRQ [range 0–100]) is used to assess health status in patients with airways obstruction. What is the minimum change in score that has been established as clinically relevant?

- a. 2 points
- b. 4 points
- c. 8 points
- d. 12 points
- e. 16 points

Answer: b. Suggested minimum clinically important difference=improvement of four or more units.

### Question 3

Olodaterol is a long-acting beta<sub>2</sub> agonist (LABA) licensed for once-daily use as maintenance bronchodilator therapy for COPD. Which one of the following bronchodilators is not licensed in the UK as monotherapy for once-daily dosing for the management of COPD?

- a. Glycopyrronium
- b. Indacaterol
- c. Salmeterol
- d. Umeclidinium
- e. Tiotropium

Answer: c. Until recently, the available LABAs were salmeterol (administered twice daily) and formoterol (usually administered twice daily). Several bronchodilators with a longer duration of action that allow once-daily administration have been developed. Those already licensed in the UK as single drug inhalers include the LAMAs glycopyrronium (▼Seebri Breezhaler), tiotropium (Spiriva) and umeclidinium (▼Incruse), and the LABA indacaterol (Onbrez Breezhaler). The LABA vilanterol is available in combination with umeclidinium (▼Anora Ellipta) or fluticasone furoate (▼Relvar Ellipta).

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#### Question 4

Two pivotal phase III randomised, double-blind, placebo-controlled trials (1222.13 and 1222.14) compared olodaterol 5µg once daily with formoterol 12µg twice daily and with placebo over 48 weeks. Which one of the following statements regarding these studies is correct?

- Study participants were required to discontinue background therapy before entering the studies
- People with severe COPD were excluded from the studies
- At 24 weeks, improvements in trough FEV<sub>1</sub> were statistically significant with olodaterol 5µg compared with placebo, but results were not clinically meaningful
- At 24 weeks, olodaterol 5µg significantly improved FEV<sub>1</sub> between 0–3 hours post-dose when compared with formoterol
- Improvements in SGRQ scores with olodaterol 5µg were statistically significant and clinically meaningful when compared with placebo

Answer: c. Olodaterol 5µg compared with placebo: difference in trough FEV<sub>1</sub>=78±21mL (p=0.0002) and 53±19mL (p<0.01) for studies 1222.13 and 1222.14, respectively. Suggested minimum clinically important difference for FEV<sub>1</sub>=100–140mL.

#### Question 5

In the pooled results of the pivotal phase III studies, what were the most common adverse effects (>4%) associated with olodaterol 5µg?

- COPD exacerbations, cough, dyspnoea, hypertension, rash, arthralgia
- Tachycardia, arrhythmia, dizziness, myocardial ischaemia, COPD exacerbations, cough
- Nasopharyngitis, upper respiratory tract infection, bronchitis, COPD exacerbations, cough, dyspnoea
- Cough, dyspnoea, tachycardia, arrhythmia, dizziness, COPD exacerbations
- Pneumonia, tachycardia, cough, arthralgia, dizziness, rash

Answer: c. Pooled evidence from the 48-week studies showed that the most common adverse effects for olodaterol 5µg included nasopharyngitis (11%), upper respiratory tract infection (8.2%), bronchitis (4.7%), COPD exacerbations (26%), cough (4.2%), and dyspnoea (4.0%).