Duaklir Genuair, the latest dry powder inhaler for COPD

Steve Chaplin BPharm, MSc

Duaklir Genuair is a twice-daily dry powder inhaler licensed as maintenance therapy for COPD. Here we present the clinical data relating to its efficacy and adverse events and discuss its place in therapy.

The long-acting antimuscarinic agent (LAMA) aclidinium bromide (Eklira Genuair) was introduced in 2012, bringing to four the number of inhaled LAMAs available as maintenance therapy for COPD – the others are tiotropium (Spiriva Respimat), glycopyrronium (Seebri Breezhaler) and umeclidinium (Incruse Ellipta). NICE recommends combining a LAMA with a long-acting beta agonist (LABA) for any patient who is breathless or continues to have exacerbations despite monotherapy with a LABA (+/- an inhaled steroid) or LAMA (see Figure 1).1 Other LAMA/LABA inhalers are Ultibro Breezhaler (glycopyronium with indacaterol) and Anoro Ellipta (umeclidinium with vilanterol), both of which are taken once daily.

Duaklir Genuair
Duaklir Genuair, a dry powder inhaler combining aclidinium (340µg/puff) and the LABA formoterol (12µg/puff), is licensed as maintenance bronchodilator treatment to relieve symptoms in adults with COPD. The recommended dose is one inhalation twice daily. No dose adjustment is recommended for older people or those with renal or hepatic impairment.

It should be used with caution in patients with cardiovascular disease or QTc interval prolongation, symptomatic prostatic hyperplasia, urinary retention or narrow-angle glaucoma. The risk of hyperkalaemia or QTc interval prolongation is increased by other drugs that share these effects.

Clinical trials
Duaklir Genuair has been evaluated in two similar 24-week Phase 3 trials (one published2), one 12-month extension trial and one 12-month trial.3

The 24-week studies included a total of 3394 patients aged ≥40 with moderate (60 per cent of patients) to severe COPD (FEV1 ≥30–<80 per cent) randomised to treatment with Duaklir Genuair, monotherapy with aclidinium or formoterol, or placebo.3 The primary endpoint was the change in FEV1 compared with baseline; other end-points included dyspnoea and quality of life scores.

In a pooled analysis of these trials, Duaklir Genuair increased trough and post-dose FEV1 by significantly more than placebo and aclidinium alone at week 24 and these differences were clinically meaningful; by contrast, the improvement compared with formoterol alone was not clinically meaningful.3 The combination also improved dyspnoea score significantly more than either monotherapy, though the difference was not clinically meaningful.
Improvement in health-related quality of life was both statistically and clinically significant compared with placebo in one study but, due to a large placebo response, not in the second. These findings are similar to outcomes reported for other LAMA/LABA preparations.\(^3\)

In the 12-month extension study, the combination increased post-dose \(\text{FEV}_1\) significantly more than placebo or either monotherapy; trough \(\text{FEV}_1\) was increased compared with placebo.\(^3\) The improvement in dyspnoea score was maintained and was greater than with formoterol. Duaklir Genuair reduced the

---

**Table 1.** NICE recommendations of the use of inhaled therapies in COPD from CG101 *Chronic obstructive pulmonary disease: Management of chronic obstructive pulmonary disease in adults in primary and secondary care (partial update)*, adapted from BNF 69 March 2015
rate of moderate to severe exacerbations compared with placebo by 20 per cent but the numerical difference was small.

The 12-month trial compared Duaklir Genuair with formoterol monotherapy. The combination increased FEV₁ by more but the difference was not clinically significant. There was no difference in exacerbation rates.

**Adverse effects**
The frequency of treatment-related adverse events associated with Duaklir Genuair was about 10 per cent – similar to that with placebo, with no difference in serious events or events causing discon- tinuation. The most frequently reported adverse events were nasopharyngitis (8 per cent) and headache (7 per cent). Conduction defects were as frequent with the combination as with formoterol alone.

**Place in therapy**
Combined LAMA/LABA inhalers are the final step in the treatment of COPD with inhaled drugs. It would be logical to prescribe these products for patients already taking one of the component drugs, in which case Duaklir Genuair may be a suitable option after formoterol. Primary care prescribing of LAMAs other than tiotropium, and that of indacaterol, is low so this may be an advantage over similar products. However, Duaklir Genuair is taken twice daily whereas other LAMA/LABA inhalers have a once daily dose. With apparently similar efficacy, a more convenient dose and patient preference for one device over another could be deciding factors.

**References**

**Declaration of interest**
None to declare.

Steve Chaplin is a pharmacist who specialises in writing on therapeutics.