



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 February 2018
EMA/CHMP/59240/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Trydonis

beclometasone dipropionate anhydrous / formoterol fumarate dihydrate / glycopyrronium

On 22 February 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Trydonis, intended for the maintenance treatment of adult patients with moderate to severe chronic obstructive pulmonary disease (COPD).

The applicant for this medicinal product is Chiesi Farmaceutici S.p.A.

Trydonis is a triple combination of an inhaled glucocorticoid (beclometasone dipropionate), a long-acting beta-2 receptor agonist (formoterol fumarate dihydrate) and a long-acting muscarinic antagonist (glycopyrronium bromide). It will be available as a pressurised metered dose inhaler delivering a solution with a nominal dose per actuation of 87 micrograms / 5 micrograms / 9 micrograms of the active substances respectively. Beclometasone reduces inflammation in the lungs, whereas formoterol and glycopyrronium relax bronchial smooth muscle helping to dilate the airways and make breathing easier (ATC code: R03AL09).

The benefits with Trydonis are its ability to relieve and prevent symptoms such as shortness of breath, wheezing and cough and to reduce exacerbations of COPD symptoms. The most common side effects of Trydonis are oral candidiasis, muscle spasm and dry mouth.

The application for Trydonis was an informed consent application. In an informed consent application, reference is made to an authorised medicine where the marketing authorisation holder of the reference medicine has given consent to the use of their dossier in the application procedure. The reference product for Trydonis is Trimbrow.

The full indication is: "Maintenance treatment in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting beta2-agonist (for effects on symptoms control and prevention of exacerbations see section 5.1)."

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion



Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.