

27 May 2021 EMA/292540/2021

Insufficient data on use of inhaled corticosteroids to treat COVID-19

EMA's COVID-19 taskforce (COVID-ETF)¹ is advising healthcare professionals that there is currently insufficient evidence that inhaled corticosteroids are beneficial for people with COVID-19.

Although the taskforce found no safety risks from studies so far, it could not exclude the possibility of harm from the use of inhaled corticosteroids in patients with COVID-19 who have normal levels of oxygen.

The advice follows a review of current evidence amid growing interest in inhaled corticosteroids (e.g. budesonide, ciclesonide) for treating outpatients with COVID-19.2,3,4

Inhaled corticosteroids are generally used for treating inflammatory conditions in the lung, such as asthma and chronic obstructive pulmonary disease (COPD). More evidence from clinical trials is necessary to establish the benefits of inhaled corticosteroids in people with COVID-19.

Current evidence from clinical trials does support the use of dexamethasone, a systemic corticosteroid, in patients with COVID-19. In September 2020, on the basis of robust data, EMA endorsed the use of oral or injectable dexamethasone in patients with COVID-19 who require supplemental oxygen therapy.

EMA will continue to monitor the use of medicines for treating or preventing COVID-19 with a view to providing up-to-date recommendations to healthcare professionals in the EU.

⁴ Covis Pharma Group announces top-line safety and efficacy data from a phase 3 placebo-controlled COVID-19 study using inhaled corticosteroid (ciclesonide). 15 April 2021 www.investegate.co.uk/article.aspx?id=20210415120000H7401, Accessed 11 May 2021.



¹ COVID-ETF is a group that brings together experts from across the European medicines regulatory network to facilitate rapid and coordinated regulatory action on medicines and vaccines for COVID-19.

² Ramakrishnan S., Nicolau D.V., Jr., Langford B., et al. Inhaled budesonide in the treatment of early COVID-19 (STOIC): a phase 2, open-label, randomised controlled trial. Lancet Respir Med, April 2021 doi:https://doi.org/10.1016/S2213-

³ Principle Collaborative Group, Yu L., Bafadhel M., et al. Inhaled budesonide for COVID-19 in people at higher risk of adverse outcomes in the community: interim analyses from the PRINCIPLE trial. MedRxiv. April 2021 https://doi.org/10.1101/2021.04.10.21254672