



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## EMA endorses use of dexamethasone in COVID-19 patients on oxygen or mechanical ventilation

EMA's human medicines committee (CHMP) has completed its [review](#) of results from the RECOVERY study arm that involved the use of the corticosteroid medicine dexamethasone in the treatment of patients with COVID-19 admitted to hospital, and has concluded that dexamethasone can be considered a treatment option for patients who require oxygen therapy (from supplemental oxygen to mechanical ventilation).

Based on the review of available data, EMA is endorsing the use of dexamethasone in adults and adolescents (from 12 years of age and weighing at least 40 kg) who require supplemental oxygen therapy. Dexamethasone can be taken by mouth or given as an injection or infusion (drip) into a vein. In all cases, the recommended dose in adults and adolescents is 6 milligrams once a day for up to 10 days.

[Published data](#) from the RECOVERY study show that, in patients on invasive mechanical ventilation, 29% of those treated with dexamethasone died within 28 days of starting dexamethasone treatment compared with 41% of patients receiving usual care, with a relative reduction of about 35%. In patients receiving oxygen without mechanical ventilation, the figures were 23% with dexamethasone and 26% with usual care, with a relative reduction of about 20%. No reduction in the risk of death occurred in patients who were not receiving oxygen therapy or mechanical ventilation. These results were supported by additional published data, including a meta-analysis conducted by the World Health Organization (WHO) which looked at data from seven clinical studies investigating the use of corticosteroids for the treatment of patients with COVID-19.

Companies that market dexamethasone medicines can request this new use to be added to their product's license by submitting an application to national medicines agencies or to EMA.

The proposed changes to the dexamethasone product information for patients and healthcare professionals are available [here](#).

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### More about the medicine

Dexamethasone is a corticosteroid medicine that has been authorised in the EU by national medicines authorities and has been available for several decades. It can be used by mouth and by injection for

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**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

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treating a range of inflammatory conditions and for reducing the body's immune response in the treatment of allergies and autoimmune diseases. It is also used with cancer medicines to treat certain cancers and to prevent vomiting. Dexamethasone was first considered a potential treatment for COVID-19 because of its ability to reduce inflammation, which plays an important role in the disease process in some patients who have been admitted to hospital with COVID-19.

### **More about the procedure**

The review of dexamethasone was started at the request of the EMA Executive Director under [Article 5\(3\) of Regulation 726/2004](#) following preliminary discussion with the COVID-19 EMA pandemic task force (COVID-ETF), which brings together experts from across the European medicines regulatory network to advise on the development, authorisation and safety monitoring of medicines and vaccines for COVID-19.

The review was carried out by EMA's Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which has now issued its scientific opinion. The CHMP's scientific opinion can be taken into account by EU member states and EMA when evaluating dexamethasone medicines for the treatment of COVID-19.