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

02.10.2020 | Circular Number P26/2020

Information on Dexamethasone

- Dexamethasone is a corticosteroid medicine used to treat certain inflammatory conditions and to reduce body's immune response in the treatment of allergies and autoimmune diseases.
- Dexamethasone is also used in the treatment of certain cancer and to prevent vomiting. Dexamethasone can be administered by mouth and by injection
- Due to its anti-inflammatory ability, Dexamethasone was considered as a potential treatment for COVID-19 patients who have been admitted to hospital.

Information from the EMA about the use of Dexamethasone in the treatment of COVID-19

The Committee for Medicinal Products for Human Use (CHMP) completed the review on Dexamethasone medicinal products on the treatment of COVID-19 patients admitted to hospital, following the results of the RECOVERY study arm. The review concluded that Dexamethasone can be used as a treatment option for patients requiring oxygen therapy (from supplemental oxygen to mechanical ventilation), in adults and adolescents (from 12 years of age and weighing at least 40 kg) at a recommended dose of 6 milligrams once a day for up to 10 days, taken by mouth or given as an intravenous (into a vein) injection or infusion (drip).

Results from the RECOVERY study (published data are available here) show that 29% of patients on invasive mechanical ventilation 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%. Patients treated with oxygen without mechanical ventilation, mortality was at 23% died in the dexamethasone group and 26% in the usual care group 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 are supported by other data, including a meta-analysis carried out by the World Health Organisation (WHO) which looked at data from seven clinical studies investigating the use of corticosteroids for the treatment of patients with COVID-19.

Companies marketing dexamethasone medicinal products can apply to national medicines agencies or to EMA to request this new use to be added to their product's license. The proposed changes to the dexamethasone product information for patients and healthcare professionals are available here.

The CHMP's scientific opinion can be considered by EU member states and EMA when evaluating dexamethasone medicines for the treatment of COVID-19.

For more information please visit the European Medicines Agency's press release on Dexamethasone.

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on Dexamethasone medicinal products. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority Form and sending it to Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 or online to **http://www.medicinesauthority.gov.mt/adrportal** or to the marketing authorisation holder or their local representatives.

Post-Licensing Directorate
Medicines Authority

Healthcare professionals and patients are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis.

Feedback Form

The Medicines Authority thanks you for the time taken to read this safety circular. The dissemination of safety circulars is an important process whereby Regulatory Authorities can communicate important issues with respect to the safety of medicines, in order to protect and enhance public health

The Medicines Authority kindly invites your anonymous feedback about the regulatory action being communicated. This may be returned by folding this formt (address side up), stapling the ends and then posting (no stamp required)

Feedback:

We thank you for your interest and look forward to hearing your opinion.

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Pharmacovigilance Section

Post-Licensing Directorate

Medicines Authority

Sir Temi Żammit Buildings

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