
Dexamethasone for treating adults with COVID 19 requiring respiratory support: EMA starts a review

19.08.2020 | Circular Number P23/2020

Information on Dexamethasone containing medicinal products

- Dexamethasone is a corticosteroid medicine which can be used to treat a range of inflammatory conditions and to reduce the body's immune response in the treatment of allergies and autoimmune diseases
- Dexamethasone is also used concomitantly with other medicines to treat certain cancers and to prevent vomiting
- Dexamethasone can be given by mouth and by injection.

In Malta products authorised through various licensing procedures, can be found in [Annex I](#).

Information from the EMA about the use of Dexamethasone in patients with COVID-19 requiring respiratory support

The Committee for Medicinal Products for Human Use (CHMP) has started a review on Dexamethasone medicinal products to treat patients with COVID-19 requiring respiratory support. The review started following results from the RECOVERY study arm, where it was observed the effect of adding dexamethasone to usual care in adult patients receiving invasive ventilation (through a machine which forces air into patient's airway through a tube), those given oxygen (e.g. through a mask) or those receiving no oxygen.

Although deaths were recorded during the 28 days following initiation of treatment with dexamethasone, preliminary results of RECOVERY also showed that dexamethasone:

- Reduced mortality by about 35% in patients on invasive mechanical ventilation
- Reduced mortality by about 20% in patients receiving oxygen without invasive ventilation
- Did not reduce death in patients who were not receiving oxygen therapy.

The review of RECOVERY results will provide an opinion on the use of dexamethasone as a potential treatment for adult patients with COVID-19.

EMA will communicate further when the review is complete.

For more information visit the European Medicines Agency's website by clicking [here](#)

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.

Annex I

Active Ingredients	Product Name	Pharmaceutical Form	Classification	Authorisation Number	Authorisation Holder
Dexamethasone 2 milligram(s)	Dexamemthasone 2mg Tablets	Tablet	POM	AA1346/00101	Antibiotic-Razgrad AD
Dexamethasone 2.0 milligram(s)	Dexamethasone Tablets BP 2.0mg	Tablet	POM	AA565/43601	Central Procurement & Supplies Unit
Dexamethasone phosphate 3.3 milligram(s)/millilitre	Dexamethasone 3.3mg/ml Solution for Injection	Solution For Injection	POM	AA734/01401	Hospira UK Limited
Dexamethasone 3.3 milligram(s)/millilitre	Dexamethasone 3.3mg/ml solution for injection	Solution For Injection	POM	AA770/01801	JV Healthcare Limited
Dexamethasone phosphate 4 milligram(s)/millilitre	Dexamed 4mg/ml solution for injection/infusion	Solution For Infusion Or Injection	POM	AA032/02703	Medochemie Limited
Dexamethasone 3.3 milligram(s)	Dexamethasone PANPHARMA Solution for Injection 3.3mg/ml (1ml amp)	Solution For Injection	POM	MA692/00401	Panpharma
Dexamethasone 6.6 milligram(s)	Dexamethasone PANPHARMA Solution for Injection 3.3mg/ml (2ml amp)	Solution For Injection	POM	MA692/00402	Panpharma
Dexamethasone sodium phosphate 4 milligram(s)	Dexamethasone Phosphate Solution for Injection 4mg/ml	Solution For Injection	POM	AA505/09601	Pfizer Hellas S.A.
Dexamethasone 2 milligram(s)	Dexamethasone 2mg/5ml Oral Solution	Oral Solution	POM	MA1296/02201	Syri Pharma Limited

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 form (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.

Postage will be paid
by the Licensee

No postage stamp
necessary if posted
in Malta and Gozo

BUSINESS REPLY SERVICE
Licence no. 656

Pharmacovigilance Section

Post-Licensing Directorate

Medicines Authority

Sir Temi Zammit Buildings

Malta Life Sciences Park

San Ġwann SĠN 3000