

Supply Disruption Alert

SDA/2021/001

Issued: 14/01/2021

Valid until: 19/04/2021

Methylprednisolone powder for solution for injection (all strengths)

Summary

- Methylprednisolone is used to treat a wide range of indications where a rapid and intense corticosteroid effect is required.
- Whilst some wholesalers are showing stocks of various presentations of methylprednisolone, there is insufficient stock in the UK to support business as usual use e.g oncology and multiple sclerosis, where robust data exist, as well as the emerging treatment of Acute Respiratory Distress Syndrome (ARDS) in COVID-19.
- Any organisations using methylprednisolone in the management of ARDS in COVID-19 patients should switch to an alternative agent.
- The alternative agents highlighted in this alert are in good supply and can support full forecasted demand.
- Stopping all ARDS use now will conserve remaining methylprednisolone stocks for business as usual use. Any intermittent supply issues will be managed nationally and supported locally by the regional pharmacy procurement specialists.
- We are working with Pfizer to review future supplies to the UK, but we anticipate that we will be unable to support additional COVID-19 demand for the foreseeable future.

Action

Where a trust identifies methylprednisolone is being used in the management of ARDS in COVID-19 patients -

The trust/hospital clinical team should:

- work with pharmacy colleagues to review current prescribing practice and switch to an alternative agent, information on alternative agents can be found in the supporting information section below;
- ensure eligible patients are receiving dexamethasone 6mg daily ie. those with COVID-19 receiving oxygen support; and
- prepare prescribing guidance to support clinical areas.

Local pharmacy teams should:

- only order methylprednisolone for 'business as usual' indications in line with that demand and no more than four days stock.

Regional and National Procurement leads should:

- work collaboratively with trust/hospitals and suppliers/distributors to challenge excessive orders of methylprednisolone;
- identify trusts and hospitals who have stock holding beyond actual demand and work with trusts to re-distribute this stock across their region; and
- support local stock sharing between trusts and hospitals where appropriate, to ensure continuity of care for patients being treated for business as usual indications.

Deadlines for actions

Actions initiated: on receipt of this alert
Actions completed: 20/1/2021

Supporting Information

Information on steroid therapy in COVID-19

Following publication of the RECOVERY¹ trial, [clinical guidelines](#) support prescribing IV dexamethasone 6mg OD for 10 days in patients requiring oxygen therapy or higher respiratory support.

Meta-analysis of data from seven clinical trials recruiting critically ill patients with COVID-19 suggests both dexamethasone and hydrocortisone (50 mg intravenously every 6 hours for seven days) reduce all-cause mortality at 28 days.

Additional information on high dose steroid treatment in ARDS (provided by UKMI, Guys and St Thomas' NHS Foundation Trust and United Kingdom Clinical Pharmacy Association (UKCPA))

Severe COVID-19 pneumonitis is characterised by hypoxaemia, progressive radiological change and a hyperinflammatory state with raised inflammatory markers which makes it similar in pathology to acute respiratory distress syndrome (ARDS). There are several trials of corticosteroids in non-COVID related ARDS. **These studies provide some support in the use of corticosteroids in ARDS patients, although a larger evidence base is needed to identify the optimal corticosteroid, dosing and timing of intervention.** The role of corticosteroids is highlighted in a consensus statement² on referral and admission of patients with severe respiratory failure to the NHS ECMO Service.

The DEXA ARDS³ study was published in March 2020 and showed benefit for using high doses of dexamethasone for ARDS in a general ICU population (20mg daily for 5 days followed by 10mg daily for 5 days).

The CO-DEX⁴ study published in September 2020 with the same dosing regimen in patients with COVID related ARDS also showed a benefit, whilst the MetCOVID⁵ study published in August 2020 used a short duration of methylprednisolone (0.5mg/kg BD for 5/7) in patients hospitalised with COVID and found little effect.

Some centres use methylprednisolone in selected ARDS patients, but with very restricted supplies available dexamethasone should be used. Enteral prednisolone in equivalent doses may also be suitable in place of methylprednisolone where the doses are not large, though there is little evidence to support the approach.

References:

1. RECOVERY Collaborative Group: 17 July 2020; DOI: 10.1056/NEJMoa2021436
2. Consensus statement: [https://www.thelancet.com/journals/lanres/article/PIIS2213-2600\(20\)30581-6/fulltext](https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(20)30581-6/fulltext)
3. DEXA-ARDS - <https://www.thelancet.com/pdfs/journals/lanres/PIIS2213-2600%2819%2930417-5.pdf>
4. CO-DEX: <https://jamanetwork.com/journals/jama/fullarticle/2770277>
5. MetCOVID - <https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciaa1177/5891816>

General information on corticosteroid use in treatment of COVID-19

- COVID-19 prescribing briefing: corticosteroids. NICE October 2020
<https://www.nice.org.uk/guidance/ng159/resources/covid19-prescribing-briefing-corticosteroids-pdf-8839913581#:~:text=Corticosteroids%20should%20not%20normally%20be,of%20%20randomised%20controlled%20trials.>
- COVID-19 therapeutic alert: Corticosteroids in the treatment of suspected or confirmed COVID-19
<https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=103092>

Distribution

Trusts (NHS boards in Scotland and Wales)

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- A&E consultants
- A&E departments
- A&E directors
- A&E nurses
- Adult intensive care units
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiology, directors of
- Cardiothoracic departments
- Cardiothoracic surgeons
- Cardiothoracic surgery directors
- Chief pharmacists
- Clinical governance leads
- Clinical Procurement Specialists
- District nurses
- Hospital at home units
- Hospital pharmacies
- Hospital pharmacists
- Immunologists
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- IV nurse specialists
- Intensive care, directors of
- Obstetricians
- Obstetrics and gynaecology departments
- Obstetrics and gynaecology directors
- Obstetrics departments
- Obstetrics nurses
- Paediatric intensive care units
- Paediatric medicine, directors of
- Palliative care teams
- Pharmaceutical advisors
- Pharmacists
- Purchasing managers
- Theatre managers
- Theatre nurses

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

Enquiries

England

Enquiries from NHS Trusts in England should in the first instance be directed to you trust pharmacy team who will escalate issues to the Regional Pharmacy Procurement Specialist and national teams if required.

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East Midlands	Andi Swain	andi.swain@nhs.net
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All other organisations should send enquiries about this notice to the DHSC Medicine Supply Team, quoting reference number **SDA/2021/001**

Email: DHSCmedicinesupplyteam@dhsc.gov.uk