

Prescribing and Medicines Optimisation Guidance

Issue: 41

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1. MHRA Drug Safety Update: Alkindi (hydrocortisone granules): Risk of adrenal insufficiency when switching formulations. ([Link](#))

When children receiving replacement therapy for adrenal insufficiency are being switched from hydrocortisone tablets to Alkindi granules, parents or carers should be informed of the need to be extra vigilant for symptoms of adrenal insufficiency.

Advice for healthcare professional is:

- Adrenal crisis has been reported in an infant who was switched from hydrocortisone soluble tablets to Alkindi (hydrocortisone granules).
- Acute adrenal insufficiency could also occur when switching from crushed hydrocortisone tablets to Alkindi granules due to a potential risk of inaccurate dosing.
- If the child is switching to Alkindi granules, parents or carers should be advised to carefully observe the child during the first week for symptoms of adrenal insufficiency, such as tiredness, floppiness, unstable temperature, headache and vomiting.
- Counsel parents or carers on what to do if the child develops symptoms of adrenal insufficiency, including the need to seek immediate medical advice and administer extra doses of Alkindi if appropriate.
- If a child requires additional doses during the first week after switching to Alkindi, a long-term increase in the daily dose of Alkindi should be considered
- Report suspected adverse drug reactions associated with hydrocortisone medicines on a Yellow Card

2. MHRA Drug Safety update: Pregabalin (Lyrica): reports of severe respiratory depression ([Link](#))

Pregabalin has been associated with reports of respiratory depression, in some cases without concomitant opioid treatment.

Healthcare professionals are advised to consider whether adjustments in dose or dosing regimen are necessary for patients at higher risk of respiratory depression, this includes people:

- with compromised respiratory function, respiratory or neurological disease, or renal impairment
- taking other CNS depressants (including opioid-containing medicines)
- aged older than 65 years

Please see the link above for the further advice.

3. MHRA Drug Safety Update: Ulipristal acetate 5mg (Esmya): further restrictions due to risk of serious liver injury ([Link](#))

The indication of ulipristal acetate 5mg for uterine fibroids has been further restricted due to the risk of serious liver injury and liver failure, with some cases requiring liver transplantation. Although the temporary suspension has been lifted, this medicine should only be used for intermittent treatment of moderate to severe symptoms of uterine fibroids before menopause and when surgical procedures (including uterine fibroid embolisation) are not suitable or have failed.

Please see the link above for the further advice.

4. GMC: Good practice in prescribing and managing medicines and devices: updated guidance 18th February 2021 ([Link](#))

The GMC have updated their ethical guidance on Good practice in prescribing and managing medicines and devices.

It will come into effect on 5 April 2021 and will support doctors who are increasingly seeing patients remotely.

Key updates include:

- new advice for doctors to stop prescribing controlled drugs without access to patient records, except in emergencies.
- stronger advice on information sharing, making it clear that if a patient refuses consent to share information with other health professionals it may be unsafe to prescribe.
- alignment with our updated 'Decision making and consent' guidance, highlighting the importance of good two-way dialogue between patients and doctors in all settings.
- updated advice on treating patients based overseas to clarify doctors may need to register in the country where they are based, where the patient is based, and where prescribed medicines are to be dispensed.

5. MHRA update: COVID-19 vaccines and medicines: updates for February 2021 ([Link](#))

The MHRA have produced a summary of advice recently issued by the MHRA relating to coronavirus (COVID-19), up to 16 February 2021. This includes:

- Yellow Card reporting data confirms safety of vaccines
- Pfizer/BioNTech vaccine: advice on six doses
- Moderna vaccine authorised for use
- Update on conditions of regulatory authorisation
- COVID-19 Therapeutic Alerts

6. PHE: COVID-19: the green book, chapter 14a – update. Last updated 12th February 2021 ([Link](#))

The green book has been updated to include:

- information on the Moderna vaccine,
- further changes to the advice on managing allergic history and allergies after the first dose
- updated information and clarification of advice on pregnancy.

**Prepared by Anita Bhardwaj, Sue Wakelin and Dr Emma Harris
On behalf of the Hampshire and IoW CCGs Medicines Optimisation Teams**

Previous bulletins can be found at:

<https://gp-portal.westhampshireccg.nhs.uk/medicines/covid-19-medicines-information/covid-19-medicines-optimisation-bulletins/>

For COVID-19 vaccine related updates, please refer to the regular NHSE&I Primary Care Bulletins.
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