East Kent Hospitals University NHS Foundation Trust

Medicines Safety Update

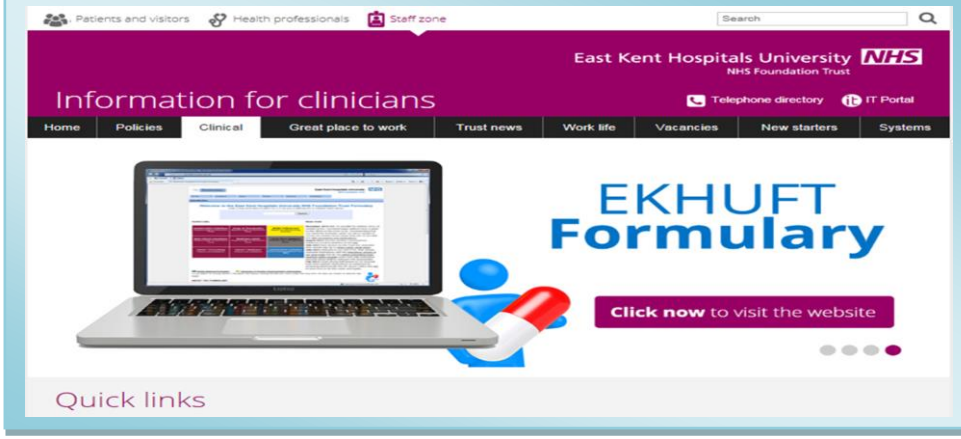
Ulipristal acetate as Esmya ®

BACKGROUND

Ulipristal acetate as Esmya® is used in 3 month courses to treat uterine fibroids. Following rare reports of serious liver injury no new patients are being initiated on the medicine while an urgent safety review takes place. Patients already on a three month course of therapy should be able to complete their course of treatment. As 56 days scripts were being used in primary care, patients will face a recall for blood tests. This issue should affect less than 50 patients in East Kent. The emergency contraceptive ellaOne® also contains ulipristal acetate (single-dose, 30mg). No cases of serious liver injury have been reported with ellaOne and there are no concerns with this medicine at this time.

More detail is in the MHRA Patient Safety Alert (https://www.cas.dh.gov.uk/ViewandAcknowledgment/ViewAttachment.aspx?Attachment_id=102937)

Patients may present to other clinical staff before they can see their GP or gynaecologist that provided last prescription, as local patient recall was first activated on 12th February 2018.



ACTION POINTS

For all clinical staff:

- For the next 4 months as patients complete their current courses of Esmya® advise users seen opportunistically of the signs or symptoms suggestive of liver injury (such as nausea, vomiting, malaise, right hypochondrial pain, anorexia, asthenia, jaundice), telling them to present to their GP if these occur.
- Check transaminase levels immediately in current or recent users of Esmya® who present with signs or symptoms suggestive of liver injury. If transaminase levels are more than 2 times the upper limit of normal, stop treatment, closely monitor and refer for specialist gastroenterology evaluation as clinically indicated.
- Reassure asymptomatic patients that they can complete their course of treatment but will need blood tests coordinated by last prescriber.
- Report any patients with liver injury on ulipristal acetate preparations via the MHRA yellow card system.

For prescribers:

- Do not commence new patients on Esmya.
- For patients on a course of Esmya, GPs and gynaecologists who last prescribed must arrange to inform patients of the signs or symptoms suggestive of liver injury, and arrange for monthly LFTs to be done with final LFT 2-4 weeks after stopping the medicine.

For further information please:
Discuss with your clinical pharmacist or call Medicines Information on 723-6001
Utilise Trust formulary to access safety information on a medicine
http://www.ekhuftformulary.nhs.uk/