Think Medicines!

NHS
Cambridgeshire and Peterborough
Clinical Commissioning Group

Issue 27
August 2019

Safety

INCREASED RISK OF PULMONARY EMBOLISM WITH TOFACITINIB (Xeljanz▼)

Even though this is a HOSPITAL only medicine, patients on this treatment may present in your practice with signs and symptoms of pulmonary embolism. It is important that you are aware of the risk factors associated with this and the urgent action to take should this situation occur.

TOFACITINIB - NEW RESTRICTION

- Tofacitinib is a HOSPITAL ONLY medication indicated for the treatment of rheumatoid arthritis and psoriatic arthritis with a recommended dose of 5 mg twice daily.
- Tofacitinib is also approved as a HOSPITAL ONLY treatment for ulcerative colitis (UC) with a recommended dose of 10mg twice daily for the first 8 weeks, and thereafter 5 mg twice daily.
- A clinical study observed an increased risk of pulmonary embolism and overall mortality with tofacitinib 10mg twice-daily in rheumatoid arthritis.
- Therefore a safety review of tofacitinib has started and new contraindications introduced.

The 10mg twice-daily dose of tofacitinib (authorised for ulcerative colitis) must NOT be used in patients at high risk of pulmonary embolism.

RISK FACTORS

The 10 mg twice daily dose must not be used in patients with one or more of the following risk factors for pulmonary embolism:

- **Use of combined hormonal contraceptives or hormone replacement therapy.**
- **Heart failure.**
- **Inherited coagulation disorder.**
- **Previous venous thromboembolism, either deep venous thrombosis or pulmonary embolism.**
- **Malignancy.**
- **Patients undergoing major surgery.**

Additionally, other risk factors should be considered when specialists are prescribing tofacitinib 10 mg twice daily including age, obesity (BMI>30), smoking and immobilisation.

Patients who are already treated with the 10 mg twice daily dose and are at high risk of pulmonary embolism should be switched to alternative treatments by their specialist.

While further assessment of the study results continues, specialists should continue to adhere to the authorised dose of 5 mg twice daily for the treatment of rheumatoid arthritis and psoriatic arthritis.

SIGNS AND SYMPTOMS

Patients receiving tofacitinib, irrespective of indication, should be monitored for the signs and symptoms of pulmonary embolism, and be advised to seek medical attention immediately if they experience them. A patient may present to your GP practice if;

- they feel pain in their chest or upper back.
- they've difficulty breathing.
- they're coughing up blood.
- they're sweating much more than usual.
- they've a lightheaded feeling, or passing out.
- they've blue lips or nails.

They may also have pain, redness and swelling in one of their legs (usually the calf).

These are symptoms of a blood clot, also called deep vein thrombosis (DVT).

For information for patients, see EMA website.

HOSPITAL ONLY MEDICINES

It is important that medicines prescribed and supplied directly by secondary care clinicians are recorded and dated on GP clinical systems.

This will ensure prescribers have all the relevant clinical information available if an adverse reactions is suspected.

Information on how to do this can be found on page 6 of the latest Joint Prescribing Group (JPG) newsletter.

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PLEASE HELP TO REVERSE THE DECLINE IN REPORTING OF SUSPECTED ADVERSE DRUG REACTIONS!

Please report to the Yellow Card Scheme any suspected adverse reactions.

MHRA DRUG SAFETY UPDATES JULY 2019

Febuxostat (Adenuric): Increased risk of cardiovascular death and all-cause mortality in clinical trial in patients with a history of major cardiovascular disease.

Avoid treatment with febuxostat in patients with pre-existing major cardiovascular disease (for example, myocardial infarction, stroke, or unstable angina), unless no other therapy options are appropriate.

Tocilizumab (RoActemra): Rare risk of serious liver injury including cases requiring transplantation.

Specialists will monitor alanine aminotransferase (ALT) and aspartate aminotransferase (AST) levels at initiation, every 4–8 weeks during the first 6 months of treatment, and every 12 weeks thereafter in patients with rheumatological indications.

Patients may present at your practice experiencing symptoms of liver injury, such as tiredness, abdominal pain, and jaundice. It is important that you speak to the patients rheumatologist immediately if you suspect liver injury.

Rivaroxaban (Xarelto▼): Reminder that 15 mg and 20 mg tablets should be taken with food.

MHRA has received a small number of reports suggesting lack of efficacy (thromboembolic events) in patients taking 15 mg or 20 mg rivaroxaban on an empty stomach; remind patients to take 15 mg or 20 mg rivaroxaban tablets with food.

Clinical systems have been updated to reflect this drug safety update and to support you in reminding patients that the 15mg and 20mg tablets should be taken with food.

Click here for letters and drug alerts sent to healthcare professionals in June 2019.

CENTRAL ALERTING SYSTEM (CAS) ALERTS

Emerade 500 microgram and 300 microgram adrenaline auto-injector devices (1st August 2019)

- There is a short term supply issue affecting Emerade 500 microgram and 300 microgram AAIs.
- Bausch & Lomb are the sole UK supplier of Emerade devices.
- New supplies of Emerade 500 microgram are expected by the end of August 2019.
- Limited stock of Emerade 300 microgram is available. Currently, new supplies are expected by the end of September 2019.
- Both Jext and EpiPen AAIs are currently available, however, supplies of Jext are unlikely to be sufficient to support a significant switch to this product and therefore where there is no patient/ clinician preference **EpiPen should be considered as the first line alternative.**
- In the absence of Emerade 500 microgram, affected patients should be prescribed 300 microgram AAIs and advised to keep at least two pens with them at all times.
- Mylan, the manufacturer of Epipen are continuing with their prescription validation process for pharmacies to order supplies of EpiPen 300 microgram. Further details are available here.
- Supplies of all 150 microgram devices (Emerade, Jext and EpiPen) are unaffected and remain available in volumes to support normal demand.

See netFormulary for further details.

DOES YOUR PRACTICE HAVE APPROPRIATE PROCEDURES IN PLACE TO ENSURE THAT ALL CLINICIANS ARE NOTIFIED OF ALERTS URGENTLY AT ALL TIMES?

It is important to review that your current process is fit for purpose especially during periods of annual leave so that all relevant clinical staff are notified of and can action alerts immediately.

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