New MHRA drug safety advice: November 2012 to January 2013

Document as included in MAW

The MHRA and CHM publish the monthly newsletter Drug Safety Update highlighting important information and advice to support the safer use of medicines. To subscribe to Drug Safety Updates from the MHRA, please visit this link to register.

The MHRA has provided the following synopsis of the key drug safety issues from the November and December 2012, and January 2013 Drug Safety Updates:

Reporting suspected adverse drug reactions to vaccines and biological medicines

To allow the MHRA to perform product/brand-specific pharmacovigilance, when reporting suspected adverse drug reactions (ADRs) to vaccines or biological medicines (such as blood products, antibodies and advanced therapies [for example gene and tissue therapy]), please ensure that the brand name (or product licence number and manufacturer) and the specific batch-number are provided in the report.

Additionally, when providing patients with details of the vaccine or biological medicine administered, it is good practice to give details of the brand and batch number. This will allow patients and carers to more accurately report suspected ADRs.

Suspected ADRs to any medicine or vaccine should be reported to the Yellow Card Scheme.

Carbamazepine, oxcarbazepine and eslicarbazepine

The risk of serious skin-related adverse drug reactions, including Stevens-Johnson syndrome, occurring with carbamazepine may be increased in the presence of the HLA-A*3101 allele in patients of European descent or Japanese origin. However, there are currently insufficient data to support screening for this allele before starting carbamazepine treatment. Patients of European descent or
Japanese origin who are known to be positive for this allele should only receive carbamazepine, oxcarbazepine or eslicarbazepine after careful consideration of the benefits and risks.

**Spray-administered fibrin sealants (Evicel)**

There have been reports of *life-threatening and fatal cases of air embolism* occurring in association with the use of spray devices employing pressure regulators to administer fibrin sealants. Such events appear to be related to the use of the spray device at higher-than-recommended pressures, and/or in closer-than-recommended proximity to the tissue surface.

Following a recent European review of the benefits and risks of these products, a number of recommendations have been made for Evicel (a brand of fibrin sealant) to minimise the risk of air embolism when this medicine is applied as a spray during surgery. These include using only CO₂ gas in the pressure regulator device, not pressurised air. Reviews of other fibrin sealants are being finalised and updated advice on these will be provided very soon.

**Fingolimod (Gilenya▼)**

Starting fingolimod treatment, or re-starting fingolimod after treatment interruption, results in transient decreases in heart rate. In some patients it can also cause transient bradycardias and heart block. This risk is minimised through enhanced monitoring.

Guidance on when enhanced cardiac monitoring is required following treatment interruption has now been updated on the basis of new clinical pharmacology analyses and dose titration data. The new monitoring advice depends both on the time since treatment started, and how long treatment has been interrupted for (see article for full details).

**Lenalidomide (Revlimid)**

Elevations of liver enzymes occur in 1 to 10 patients out of every 100 treated with lenalidomide for multiple myeloma in clinical trials; the majority of these are non-serious. Overall, *serious (potentially fatal) liver injuries* such as acute hepatic failure, toxic hepatitis, hepatocellular hepatitis, and cholestatic hepatitis have been reported in less than 1% of treated patients.

Hepatic function should be routinely monitored (with the same frequency as haematological monitoring), particularly in patients with a history of, or concurrent, viral liver infection, or when lenalidomide is given at the same time as other medications known to be associated with liver injury.

**Roflumilast (Daxas▼)**

Roflumilast is known to be associated with an *increased risk of psychiatric disorders*. It is not recommended for patients with a history of depression associated with suicidal ideation or behaviour.

Patients and caregivers should be asked to notify the prescriber and their healthcare provider of any changes to behaviour or mood, and any suicidal ideation. Such symptoms include preoccupation with suicidal thoughts, and self-harm.

Roflumilast should be discontinued if new or worsening psychiatric symptoms or suicidal behaviour are identified.
Other topics

- Other topics covered for which further details can be found on the Drug Safety Update page of the MHRA website include:

- Human papillomavirus vaccine Cervarix: positive benefit-risk balance confirmed at end of routine use in national HPV immunisation programme

- MHRA antipsychotics learning module approved for continuing professional development

- Codeine-containing pain relief in children: reports of fatalities with post-surgical use, and risk of ultra-rapid metabolism

- End of year quiz on drug safety

- Tredaptive (combined niacin-laropiprant): – no longer for prescribing since preliminary HPS2-THRIVE trial failed to show benefit outweighs risks

- Yellow Card reporting and pharmacovigilance learning module

- New MHRA Twitter channel on safety of medicines.

The process used to produce Drug Safety Update is NICE accredited.

References

1. Drug Safety Update November 2012, vol 6, issue 4: H1
2. Drug Safety Update December 2012, vol 6, issue 5: A1
3. Drug Safety Update December 2012, vol 6, issue 5: S1
8. Drug Safety Update November 2012, vol 6, issue 4: O1
10. Drug Safety Update December 2012, vol 6, issue 5: O1
11. Drug Safety Update January 2013, vol 6, issue 6: S1
12. Drug Safety Update January 2013, vol 6, issue 6: O1

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