



If you would like to receive this bulletin by email contact: [swb-tr.SWBH-YCCWestMidlands@nhs.net](mailto:swb-tr.SWBH-YCCWestMidlands@nhs.net)

## Bikini diet on hold: diclofenac found in weight loss supplement

The FDA has reported that Lucy's Weight Loss System have voluntarily recalled all lots of Pink Bikini White powder capsules. This followed FDA sampling and testing that found the pills positive for diclofenac.

Earlier in the year Lucy's Weight Loss System issued a similar voluntary recall due to undeclared sibutramine and phenolphthalein. Sibutramine is an appetite suppressant that had its European licence suspended in 2010. The cardiovascular risks such as myocardial infarction and stroke outweighed the modest effects on weight loss. Phenolphthalein was previously used as a laxative; however, it is no longer authorised because of possible links with cancer.

Herbal medications, weight loss supplements and medication purchased on the internet may contain harmful ingredients. Please report any adverse reactions or adulteration to the MHRA on a Yellow Card: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

## No sugar pills: new diabetes medications have safety warnings

The FDA has warned that the DPP-4 inhibitors sitagliptin, saxagliptin, linagliptin and alogliptin may cause joint pain that can be severe and disabling.

Meanwhile, MHRA has warned that the SGLT2 inhibitors (canagliflozin, dapagliflozin, empagliflozin) unexpectedly carry an increased risk of diabetic ketoacidosis in patients with Type II diabetes, which is sometimes serious and life threatening. Blood glucose concentrations may be only moderately elevated, which is unusual.

▼ Recently marketed drugs are intensively

monitored. Please report all adverse drug effects to Black Triangle drugs to the MHRA on a Yellow Card.

## Yellow Card app: Digital evolution

The MHRA launched the Yellow Card app on the 14<sup>th</sup> July 2015. The free-to-access mobile app for iOS and Android devices is a convenient alternative for Yellow Card reporting. It allows users to create a 'watch list' of medications about which they receive news and alerts. Being able to view the numbers of Yellow Cards received by MHRA for medicines of interest, and provide updates to Yellow Cards already submitted are also new features.

The app should prove useful to clinicians, as there is quick and easy access to comprehensive information on adverse drug reactions. Download the app from the [iTunes App Store](https://itunes.apple.com/gb/app/yellow-card-reporting-app/id985111111) and [Google Play](https://play.google.com/store/apps/details?id=org.mhra.yellowcard) for your IOS or Android device.



## Pain in the backside: Nicorandil and ulcers

The manufacturer of nicorandil have written to healthcare professionals stating that nicorandil can cause serious skin, mucosal, and eye ulceration, which persists unless treatment is discontinued.

Watson et al described peri-anal ulcers with nicorandil in 5 patients (Lancet 2002; 360: 546-7). Later Baker et al (Tech Coloproctol 2007; 11(4): 343-5) described 11 patients, 9 of whom had undergone surgery before the association with nicorandil was recognized.

Mouth ulceration is a common adverse effect of nicorandil; however, ulceration can occur anywhere in the gastrointestinal tract, the genital region, and

the skin. Recently, corneal ulcers have been described. Nicorandil-induced ulcers are refractory to treatment including surgery, but heal when the drug is stopped. Adverse reactions can sometimes be hard to diagnose—unless the possibility is considered. Please report adverse drug reactions on a Yellow Card.

## **Royal College of General Practitioners/Royal Pharmaceutical Society Joint meeting: working together in general practice**

The Yellow Card Centre West Midlands hosted the RPS/ RCGP West Midlands inaugural joint educational meeting.

Doctors and pharmacists presented cases to show how multidisciplinary working can detect and mitigate drug-related harm. We hope that future developments with pharmacists working in GP practices will heighten awareness of medication safety issues in primary care and improve patient safety.

## **Heard the new bisphosphonate update? Osteonecrosis of the auditory canal with bisphosphonates**

There have been reports of osteonecrosis of the external auditory canal in association with bisphosphonates.

Most cases were associated with bisphosphonate therapy lasting two years or more. The possibility of this adverse drug reaction should be considered in patients who present with ear symptoms, including chronic ear infections.

If you suspect an adverse drug reaction please report to the MHRA.

## **Thank you**

The Yellow Card Centre and the ADR champions would like to wish all of our reporters a Happy New Year. The monitoring of drug safety depends on the goodwill of those who report adverse drug reactions to the Yellow Card Scheme, and we are very grateful for their efforts.

The efforts of the doctors, nurses, pharmacists and patients in the West Midlands has made the past year one of our most successful years in terms of collecting reports.

Each card adds a little more to our knowledge of drug safety. Please visit our website [www.yccwm.org.uk](http://www.yccwm.org.uk) or follow us on twitter <https://twitter.com/yellowcardwm> and remember our motto:

**“If in doubt, fill one out.”**

---

## **The Yellow Card Centre West Midlands**

### **Reporting guidelines for healthcare professionals**

Yellow Cards can be used for reporting suspected adverse drug reactions to medicines, vaccines, herbal or complementary products, whether self-medicated or prescribed. This includes suspected adverse drug reactions associated with misuse, overdose, medication errors or from use of unlicensed and off-label medicines.

### **Report all suspected adverse drug reactions that are:**

- **Serious, medically significant or result in harm. Serious events are fatal, life-threatening, a congenital abnormality, disabling or incapacitating, or resulting in hospitalisation.**
- **Associated with newer drugs and vaccines ( ▼ ); the most up-to-date list of black triangle medicines is available at: [www.mhra.gov.uk/blacktriangle](http://www.mhra.gov.uk/blacktriangle)**

If in doubt whether to report a suspected adverse drug reaction, please complete a Yellow Card.

Adverse drug reactions where harm occurs as a result of a medication error are reportable as a Yellow Card or through the local risk management systems into the National Reporting and Learning System (NRLS). If reported to the NRLS, these will be shared with the MHRA. If the NRLS is not available and harm occurs, report using a Yellow Card.

It's quickest to send a Yellow Card to the MHRA online: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or please send reports to: 'FREEPOST YELLOW CARD' (no stamp or any other address details are needed). If you would like a supply of pre-addressed and reply-paid Yellow Cards, please contact us:

**Phone:** 0121 507 5672 **Email:** [swb-tr.SWBH-YCCWestMidlands@nhs.net](mailto:swb-tr.SWBH-YCCWestMidlands@nhs.net)

**Address:** Yellow Card Centre West Midlands, Pharmacy, City Hospital, Dudley Road, Birmingham, B18 7QH.

Please send any comments to:

Professor R E Ferner at West Midlands Centre for Adverse Drug Reaction Reporting, or email: [r.e.ferner@bham.ac.uk](mailto:r.e.ferner@bham.ac.uk)