

Drug Safety Update



Latest advice for medicines users

The monthly newsletter from the Medicines and Healthcare products Regulatory Agency and its independent advisor the Commission on Human Medicines

Volume 10 Issue 10 May 2017

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The Medicines and Healthcare products Regulatory Agency is the government agency which is responsible for ensuring that medicines and medical devices work, and are acceptably safe.

The Commission on Human Medicines gives independent advice to ministers about the safety, quality, and efficacy of medicines. The Commission is supported in its work by Expert Advisory Groups that cover various therapeutic areas of medicine.



The MHRA is accredited by NICE to provide Drug Safety Update. Further information can be found on the NICE Evidence Search portal:
www.evidence.nhs.uk/

We have received rare reports of depression and suicidal thoughts in men taking finasteride 1 mg (Propecia) for male pattern hair loss (page 2). Advise patients to stop finasteride 1 mg (Propecia) immediately if they develop depression and inform a healthcare professional. Be aware that depression is also associated with finasteride 5 mg (Proscar).

Also this month, we feature news of e-learning modules on the importance of reporting suspected adverse reactions (page 3). Using the new free e-learning module, all healthcare professionals can learn about when and how to report suspected adverse drug reactions. Doctors can use the module to gain CPD credits. Specific modules with CPD credits are also available for nurses and pharmacists. Healthcare professionals who report suspected adverse reactions to us via the Yellow Card Scheme help us to monitor and improve the safety of medicines, vaccines, and medical devices.

In our third article (page 5), find letters sent to healthcare professionals in April 2017, including an important reminder about the withdrawal of the epilepsy medicine retigabine (Trobal) from the market that advises how patients should be withdrawn by the end of June 2017.

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Finasteride: rare reports of depression and suicidal thoughts

We have received reports of depression and, in rare cases, suicidal thoughts in men taking finasteride 1 mg (Propecia) for male pattern hair loss. Be aware that depression is also associated with finasteride 5 mg (Proscar).

Advice for healthcare professionals:

- since finasteride has been marketed there have been a number of spontaneous adverse drug reaction reports suggesting a possible link to depression, and in rare cases, suicidal thoughts
- advise patients to stop finasteride 1 mg (Propecia) immediately if they develop depression and inform a healthcare professional
- be aware that the product information for finasteride 5 mg (Proscar) already lists depression as a possible adverse reaction

Background

Finasteride is a 5 α -reductase-type-2 inhibitor. In the 1 mg dose (Propecia), it is indicated for the treatment of male pattern hair loss (androgenetic alopecia). In the 5 mg dose (Proscar), it is indicated for the treatment and control of benign prostatic hyperplasia.

Reports of major depression and suicidal thoughts

Some men have reported episodes of depressive illness in association with the use of Propecia for male pattern hair loss. Some men also reported having suicidal thoughts.

Depression and suicidal thoughts have been reported in men with and without a previous history of depression.

Depressed mood has been previously recognised with Propecia. A recent review of the evidence has suggested more significant depression can occur and so the advice is being updated to reflect this.

The product information for Proscar already lists depression as a possible adverse reaction and is being updated in light of a recent review.

Sexual dysfunction

Healthcare professionals are reminded that adverse reactions related to sexual function have been reported in association with finasteride. These include decreased libido, erectile dysfunction, and ejaculation disorders (such as decreased volume of ejaculate).

Reporting of suspected adverse reactions

Suspected adverse reactions should be reported to us via the [Yellow Card Scheme](#).

Article citation: Drug Safety Update volume 10 issue 10, May 2017: 1.

New CPD e-learning module on reporting suspected adverse drug reactions

You can use our free e-learning modules to find out more about how and when to report suspected adverse drug reactions and earn CPD credits at the same time.

e-learning modules available

We have created a new [free e-learning module](#) for all healthcare professionals to learn about the importance of reporting suspected adverse drug reactions (ADRs).

The European Accreditation Council for Continuing Medical Education (EACCME), an institution of European Union of Medical Specialists (UEMS), has given the module the highest order of accreditation. Doctors are awarded 1 EACCME credit (1 hour) on completion of the 45 minute ADR e-learning module.

Please complete this [short survey](#) upon completion of the ADR e-learning module so that we can capture your feedback and further improve the learning module.

Other e-learning modules on ADRs are also available specifically for [pharmacists](#) and [nurses](#) and these also count for Continuing Professional Development (CPD) credits.

Importance of Yellow Card reporting

Prompt reporting to the MHRA's [Yellow Card Scheme](#) helps to make medicines, vaccines, and medical devices safer.



Reporting ADRs is part of the responsibilities of healthcare professionals and their team. These responsibilities include informing patients and carers about how they can help by reporting suspected side effects themselves. Duplicate reports can be detected by our systems so please do not hesitate to complete a Yellow Card report.

The quickest way to send a report is through the [Yellow Card website](#); SystmOne, Vision, and MiDatabank clinical software systems; or the free Yellow Card app (for [iOS](#) and [Android](#)).

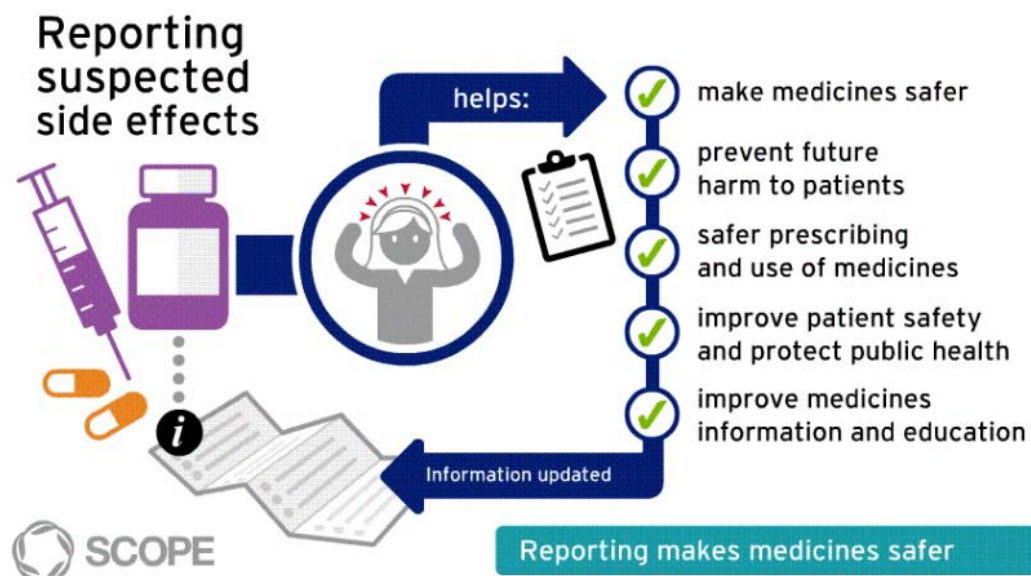
Yellow Cards act as an early warning system to help the MHRA to identify and characterise important safety issues, many of which were not recognised as being related to a particular medicine until reports were received.

Help us to raise awareness

We created the new e-learning module for healthcare professionals as part of the Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) Joint Action project. A survey by SCOPE found that many EU countries did not have a specific online e-learning module on ADRs to support healthcare professionals and encourage reporting.

The e-learning module forms part of a [toolkit](#) to raise awareness about reporting suspected ADRs. The toolkit also includes [supporting infographics](#) and an animation that summarises how the Yellow Card scheme works.

Below is an infographic from SCOPE about how reporting suspected side effects can make medicines safer.



You can help to raise awareness about the importance of reporting suspected adverse effects by sharing these materials on social media, linking to www.mhra.gov.uk/yellowcard, and using the hashtag #patientsafety.

Article citation: Drug Safety Update volume 10 issue 10, May 2017: 2.

Letters sent to healthcare professionals in April 2017, including a reminder of the retigabine (Trobal) withdrawal

In [September 2016](#) we told you about the withdrawal of retigabine (Trobal) from the market.

In April 2017, [a letter](#) was sent reminding relevant healthcare professionals that all patients must be withdrawn from Trobal **by the end of June 2017**.

Withdrawal of a patient should be gradual and take place over at least 3 weeks, in accordance with the prescribing information.

Letters were also sent about the following medicines in April 2017:

- Orgalutran (ganirelix) 0.25 mg/0.5 mL: [temporary shortage](#)
- Cotellic▼ (cobimetinib): [important additional warnings for haemorrhage and rhabdomyolysis](#), including dose modification recommendations
- Floran (epoprostenol): [reminder of replacement of Flolan \(with Solvent pH 10.5\) with Flolan \(with Solvent pH 12\)](#)
- ERWINASE 181G: [notice of special handling instructions](#)—vials of ERWINASE from batch 181G should be used with a 5-micron filter needle
- Levetiracetam-containing products 100 mg/mL oral solution presentations: [risk of medication errors associated with overdose](#)
- Amoxil (amoxicillin trihydrate): [updated dosing recommendations for patients undergoing haemodialysis](#)

Article citation: Drug Safety Update volume 10 issue 10, May 2017: 3.