

Drug Safety Update



Latest advice for all medicines users

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

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Every month, Drug Safety Update aims to bring you the latest advice to support safer prescribing and use of medicines—ie, news on contraindications for medicines, their recommended dose, and special warnings or precautions for use. Adherence to the prescribing information for a medicine, in addition to keeping up to date with our guidance in Drug Safety Update, helps to optimise safe use of a medicine.

However we understand that many of you may face difficult treatment decisions. Sometimes there may be clinical situations when the use of a medicine outside the terms of its licence (ie, off-label) or use of an unlicensed medicine may be judged by the prescriber to be in a patient's best interests on the basis of the available evidence. Our article on p 6 outlines the responsibilities when prescribing a medicine off-label or using an unlicensed medicine.

A drug-safety advice article (p 3) this month highlights the risk of CNS toxicity with methylthioninium chloride, which is licensed for the treatment of drug-induced methaemoglobinaemia. We are aware of 33 reports of a suspected interaction between methylthioninium chloride and recent treatment with serotonergic drugs, leading to CNS toxicity. In all cases, patients were receiving methylthioninium chloride outside its licensed indication, and we ask prescribers to be aware of the risk from this suspected interaction.

Paediatrics is a specialism where medicines might be used unlicensed or used off-label due to difficulties in the development of age-appropriate formulations. The MHRA is working hard to improve the availability of high-quality, ethically researched, and properly authorised medicines for children (see Drug Safety Update January 2009, p 7; www.mhra.gov.uk/mhra/drugsafetyupdate). Our second Hot topic this month highlights that many medicines given to children have not been properly studied in this population—including those available over-the-counter. After a review of the available data, we have issued new advice to improve the safe use of cough and cold medicines for children younger than 12 years (p 8). Please report suspected adverse drug reactions in children, even when a medicine has been used off-label or is unlicensed.

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 safety, quality, and efficacy of medicines. The Commission is supported in its work by Expert Advisory Groups that cover various therapeutic areas of medicine.

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Drug safety advice

Antiepileptics: adverse effects on bone

Keywords: antiepileptics, carbamazepine, phenytoin, phenobarbital, primidone, sodium valproate, bone mineral density, osteopenia, osteoporosis, osteomalacia, fractures

The available data suggest that long-term use of carbamazepine, phenytoin, primidone, and sodium valproate is associated with decreased bone mineral density that may lead to osteopenia, osteoporosis, and increased fractures in at-risk patients. Vitamin D supplementation should be considered for at-risk patients who are taking these medicines long term

The antiepileptic drugs carbamazepine, phenytoin, primidone, and phenobarbital are known to cause osteomalacia, and the product information for healthcare professionals for these drugs contains information about this risk. Osteoporosis is also a recognised side-effect of carbamazepine.

A recent review of data from published preclinical studies,¹ epidemiological studies,^{2,3} and UK Yellow Card data found that long-term treatment with carbamazepine, phenytoin, and primidone, and in addition long-term treatment with sodium valproate, is associated with decreased bone mineral density that results in an increased risk of developing osteopenia, osteoporosis, and fractures in the following at-risk patients:

- those who are immobilised for long periods
- those who have inadequate sun exposure
- those with inadequate dietary calcium intake

There is limited understanding of the effects of antiepileptics on bone. Some evidence suggests that antiepileptics (including phenytoin, phenobarbital, carbamazepine, and primidone) induce the cytochrome P450 enzyme system, which results in increased clearance of vitamin D, leading to secondary hyperparathyroidism, increased bone turnover, and reduced bone density. The mechanism by which sodium valproate, a non-enzyme-inducing drug, causes decreased bone mineral density is unclear.

At present there are insufficient data to support an association between decreased bone mineral density, osteopenia, osteoporosis, and osteomalacia and other antiepileptic drugs.

Advice for healthcare professionals:

- The available data suggest that phenytoin, carbamazepine, primidone, and sodium valproate are associated with decreased bone mineral density, which may lead to osteopenia, osteoporosis, and increased fractures in at-risk patients
- Phenytoin, carbamazepine, phenobarbital, and primidone are associated with an increased risk of osteomalacia
- Vitamin D supplementation should be considered for at-risk patients who receive long-term treatment with primidone, phenytoin, carbamazepine, phenobarbital, or sodium valproate

Access Summaries of Product Characteristics for these at <http://emc.medicines.org.uk/>

1 Pack AM, et al. *Cleve Clin J Med* 2004; 71 (suppl 2): S42–48.

2 Vestergaard P, et al. *Acta Neurol Scand* 2005; 112: 277–86.

3 Petty SJ, et al. *Neurology* 2005; 65: 1358–63.

Has your
colleague seen
this bulletin?

Methylthionium chloride (methylene blue): update on CNS toxicity with serotonergic drugs

Keywords: encephalopathy, intractable hypotension, interaction, methylthionium chloride, methylene blue, neurotoxicity, parathyroidectomy, serotonergic antidepressant, serotonin reuptake inhibitor, SSRI

Methylthionium chloride (methylene blue) in high intravenous doses should be avoided for patients being treated with serotonergic antidepressants (eg, SSRIs, clomipramine, and venlafaxine)

See Drug Safety Update January 2008, p 5;
www.mhra.gov.uk/mhra/drugsafety/update

Methylthionium chloride (formerly called methylene blue) is approved for the management of drug-induced methaemoglobinaemia in adults. It is also used for other purposes, but these uses are not covered by the product licence.

On the basis of 27 reports of CNS toxicity associated with methylthionium, the January 2008 issue of Drug Safety Update advised how the risk could be minimised. The Summary of Product Characteristics for methylthionium chloride has now been updated to mention the possibility of CNS toxicity in patients being treated with serotonergic drugs such as selective serotonin reuptake inhibitor (SSRI) antidepressants, clomipramine, and venlafaxine. Features of toxicity include confusion, disorientation, agitation, expressive aphasia, altered muscle tone in limbs, hypoxia, ocular symptoms, and depressed level of consciousness.

All cases reviewed described CNS toxicity after the use of methylthionium as a visualising agent in parathyroid or thyroid surgery. Since the review, further cases of CNS toxicity in association with methylthionium have come to light. Five of the new cases involved parathyroid surgery (two cases reported to us on Yellow Cards and three documented in the literature¹⁻³). However, a further new case of CNS toxicity involved the use of methylthionium for management of uncontrollable hypotension during cardiac surgery.⁴

In all new cases, the patients were being treated with either an SSRI antidepressant or clomipramine, and the features of toxicity were similar to those reported previously. In four cases, the reporters labelled the reaction as serotonin syndrome. These additional reports—which bring the total number of cases to 33—reinforce the possibility that CNS toxicity results from an interaction between a serotonergic drug and methylthionium. When reporting a suspected adverse drug reaction to us on a Yellow Card, it is helpful if you can give information on the patient's outcome; this helps us prioritise the information.

As with visualisation in surgical procedures, the management of intractable hypotension is not an approved indication for methylthionium chloride.

In view of these new reports, we have strengthened the advice for healthcare professionals.

For further information on the Yellow Card Scheme see www.yellowcard.gov.uk

1 Khan MAS, et al. *Ann R Coll Surg Engl* 2007; **89**: 1–3.

2 Ng BKW, et al. *Can J Anesth* 2008; **55**: 36–41.

3 Khavandi A, et al. *Med J Aust* 2008; **189**: 534–35.

4 Shanmugam G, et al. *Interact Cardiovasc Thorac Surg* 2008; **7**: 656–58.

Advice for healthcare professionals:

- Methylthionium chloride by the intravenous route is approved only for drug-induced methaemoglobinaemia in adults at a dose of 1–2 mg/kg
- Off-label use of methylthionium (including use in parathyroid localisation or its use at doses exceeding the licensed dose) should be carefully evaluated in view of the potential for CNS toxicity
- Intravenous methylthionium chloride should be avoided in patients who have been treated recently with serotonergic antidepressants, including SSRIs, clomipramine, and venlafaxine
- If use of intravenous methylthionium chloride cannot be avoided, the lowest possible dose should be used and the patient observed closely for CNS effects for up to 4 hours after administration
- If features of CNS toxicity develop after use of methylthionium, the patient should be monitored closely and given supportive care

Yellow Card Scheme update

The Yellow Card scheme collects information on suspected adverse drug reactions. See www.yellowcard.gov.uk

See Drug Safety Update September 2008, p 5; www.mhra.gov.uk/mhra/drugsafetyupdate

For information on the national HPV programmes in England, Scotland, Wales, and Northern Ireland, please refer to the respective websites:

England: <http://www.immunisation.nhs.uk/Vaccines/HPV>

Scotland: <http://www.fightcervicalcancer.org.uk/>

Wales: <http://new.wales.gov.uk/beatcervicalcancer/home/?lang=en>

Northern Ireland: <http://www.helpprotectyourself.info/>

Human papillomavirus immunisation programme—safety update

The UK immunisation programme against human papillomavirus (HPV) began last Autumn. The routine programme is mainly school-based and is targeted at girls aged 12–13 years. In addition, a phased catch-up programme for girls aged up to 18 years is in place. Cervarix is the vaccine being used, which provides protection against HPV types 16 and 18 after a course of three doses (at 0, 1, and 6 months, respectively).

HPV infection is one of the most common sexually transmitted diseases. It causes nearly 3000 cases of cervical cancer in the UK every year. HPV types 16 and 18 are responsible for approximately 70% of all cases of cervical cancer. The UK immunisation programme could eventually prevent up to 400 deaths per year.

As with all vaccines and medicines, the MHRA is responsible for monitoring the safety of Cervarix in the UK.

Monitoring of HPV vaccine safety

Guidance on reporting suspected adverse reactions via the Yellow Card Scheme was outlined in the September 2008 issue of Drug Safety Update. Further information is available on our website at www.mhra.gov.uk/HPVvaccine.

The MHRA analyses Yellow Cards received for Cervarix on a daily basis and publishes a weekly assessment of these data on the above webpage. Reports are placed into one of five categories: injection-site reactions; possible allergic reactions; other recognised/known adverse reactions; psychogenic events (eg, needle phobia reactions such as faints); and suspected reactions not currently recognised to be associated with Cervarix.

The picture so far...

Across the UK, at least 700 000 doses have been administered so far. As at March 19, 2009, MHRA had received 1454 Yellow Cards, including 3209 adverse-reaction terms, in association with Cervarix (including reports in which the brand of HPV vaccine was not stated by the reporter, but most of which can be expected to be Cervarix). As expected, most Yellow Card reports have been submitted by nurses (mainly school nurses).

The ten most commonly reported suspected adverse reactions as of March 19, 2009 were:

Suspected adverse reaction	Number of reports	Suspected adverse reaction	Number of reports
1. Dizziness	363	6. Malaise	115
2. Nausea	310	7. Vomiting	109
3. Headache	288	8. Fatigue	70
4. Pain in extremity (mainly sore arm)	154	9. Rash	66
5. Syncope	150	10. Pallor	62

Yellow Card scheme update

continued

Most suspected adverse reactions reported to MHRA in association with Cervarix relate to signs and symptoms of recognised reactions that are listed in the product information: 14% were injection-site reactions; 9% were possible allergic events; and 37% were other recognised/known adverse reactions. The cases reported to the MHRA do not indicate any change in the known severity or nature of such reactions.

'Psychogenic' events have accounted for 30% of all adverse reactions reported. These include vasovagal syncope, faints, and panic attacks, which can occur with any injection procedure—not only vaccination. These events are due to fear or anticipation of the needle injection and are not side-effects of Cervarix.

The remaining 10% of suspected reactions received are not known reactions to Cervarix and may have been coincidental with vaccination; the available evidence does not suggest a causal link with the vaccine.

The number and nature of suspected adverse reactions received so far is very much in line with what we expected to receive at this time. The Commission on Human Medicines (CHM) reviewed these data in February 2009 and agreed that no new or serious risks have been identified during use of Cervarix in the UK, and that the balance of benefits and risks remains positive. The MHRA and CHM will continue to monitor the safety of Cervarix during use in the UK.

Many girls will currently or shortly be receiving the third dose of Cervarix. It is essential that all three doses are given to ensure protection. Please continue to report any suspected adverse reactions associated with Cervarix via the Yellow Card Scheme, either by post or online at www.yellowcard.gov.uk. Thank you to those who have sent us Yellow Cards for Cervarix. Remember that parents and vaccinees can also report via the Yellow Card Scheme.

For further information see
www.yellowcard.gov.uk

Hot topics

Read Summaries of Product Characteristics at <http://emc.medicines.org.uk/>

Read more about medicines for children <http://www.mhra.gov.uk/Howweregulate/Medicines/Medicinesforchildren/index.htm>; see also Drug Safety Update January 2009, p 7; www.mhra.gov.uk/mhra/drugsafetyupdate

Guidance

General Medical Council Good Practice in Prescribing Medicines (September 2008): http://www.gmc-uk.org/guidance/current/library/prescription_faqs.asp

Royal Pharmaceutical Society of Great Britain Pharmacist Prescriber's Pack: <http://www.rpsgb.org.uk/worldofpharmacy/currentdevelopmentsinpharmacy/pharmacistprescribing/index.html>

Nursing and Midwifery Council standards of proficiency for nurse and midwife prescribers (April 2006): <http://www.nmc-uk.org/aDisplayDocument.aspx?documentID=1645>; and NMC standards for medicines management (February 2008): <http://www.nmc-uk.org/aDisplayDocument.aspx?documentID=4585> (summary).

Health Professions Council: <http://www.hpc-uk.org/>

General Dental Council: <http://www.gdc-uk.org/Our+work/Standards/>

Department of Health, Medicine Matters (July 2006): http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_064325

Off-label use or unlicensed medicines: prescribers' responsibilities

A licensed medicine meets acceptable standards of efficacy, safety, and quality

A marketing authorisation or product licence defines a medicine's terms of use: its Summary of Product Characteristics outlines, among other things, the indication(s), recommended dose(s), contraindications, and special warnings and precautions for use on which the licence is based, and it is in line with such use that the benefits of the medicine have been judged to outweigh the potential risks. Furthermore, a licensed medicine: has been assessed for efficacy, safety, and quality; has been manufactured to appropriate quality standards; and when placed on the market is accompanied by appropriate product information and labelling.

Prescribing in a patient's best interests

However, there are clinical situations when the use of unlicensed medicines or use of medicines outside the terms of the licence (ie, 'off-label') may be judged by the prescriber to be in the best interest of the patient on the basis of available evidence. Such practice is particularly common in certain areas of medicine: for instance, in paediatrics where difficulties in the development of age-appropriate formulations means that many medicines used in children are used off-label or are unlicensed.

Healthcare professionals may regard it necessary to prescribe or advise on the use of an unlicensed medicine (ie, through the so-called 'specials' regime when no licensed suitable alternative is available, or when a medicine is prepared in a pharmacy by, or under the supervision of, a pharmacist), or the use of a licensed medicine outside the terms defined by the licence (eg, outside defined indications, doses, routes of administration, or contrary to listed warnings).

In practice

At present, the following healthcare professionals can prescribe an unlicensed medicine: doctors; dentists; and, in some circumstances, supplementary prescribers (who can be a pharmacist, nurse, midwife, community nurse, optometrist, physiotherapist, radiographer, or chiropodist/podiatrist). In addition to these health professional groups, the following can prescribe a licensed medicine off-label: nurse independent prescribers, pharmacist independent prescribers, and optometrist independent prescribers. However, all healthcare professionals who can prescribe as outlined above are subject to: their individual clinical competence; the professional codes and ethics of their statutory bodies; and the prescribing policies of their employers.

The responsibility that falls on healthcare professionals when prescribing an unlicensed medicine or a medicine off-label may be greater than when prescribing a licensed medicine within the terms of its licence. Prescribers should pay particular attention to the risks associated with using unlicensed medicines or using a licensed medicine off-label. These risks may include: adverse reactions; product quality; or discrepant product information or labelling (eg, absence of information for some unlicensed medicines, information in a foreign language for unlicensed imports, and potential confusion for patients or carers when the Patient Information Leaflet is inconsistent with a medicine's off-label use).

Examples of off-label use of medicines

Off-label intravitreal use of **bevacizumab** (Avastin, licensed for treatment of various solid cancers) has been associated with reports of severe eye inflammation and

Hot topics *continued*

See letter to healthcare professionals sent February 2009 at

<http://www.mhra.gov.uk/Safetyinformation/Safetywarningsalertsandrecalls/Safetywarningsandmessagesformedicines/Monthlylistsofinformationforhealthcareprofessionalsonthesafetyofmedicines/CON041210>

See this issue p 3.

See letter sent to healthcare professionals June 2008 at

<http://www.mhra.gov.uk/Safetyinformation/Safetywarningsalertsandrecalls/Safetywarningsandmessagesformedicines/Monthlylistsofinformationforhealthcareprofessionalsonthesafetyofmedicines/CON018263>

Further information

MHRA

Drug Safety Update brings you the latest information about changes to prescribing information to support safer use of medicines:

www.mhra.gov.uk/mhra/drugsafetyupdate; register to receive an email alert when a new issue is published by emailing registration@mhradrugsafety.org.uk

Review of unlicensed medicines: <http://www.mhra.gov.uk/Howweregulate/Medicines/Reviewofunlicensedmedicines/index.htm>

Importation of unlicensed medicines: <http://www.mhra.gov.uk/Howweregulate/Medicines/Importingandexportingmedicines/importingunlicensedmedicines/index.htm>

Consent

Key documents from the Department of Health:

<http://www.dh.gov.uk/en/Publichealth/Scientificdevelopmentgeneticsandbioethics/Consent/Consentgeneralinformation/index.htm>

British National Formulary and British National Formulary for Children:

www.bnf.org and www.bnfc.org

Royal College of Paediatrics and Child Health:

<http://www.rcpch.ac.uk/>

sterile endophthalmitis. The production methods, formulation, and doses for bevacizumab were developed for use in oncology. Its use in the ophthalmology setting has not been authorised.

Methylthioninium chloride (methylene blue) is authorised for management of drug-induced methaemoglobinaemia; however, it is sometimes used off-label as a visualising agent during parathyroid surgery. We are aware of 33 reports of a suspected interaction between methylthioninium chloride and recent treatment with serotonergic drugs, leading to CNS toxicity. In all cases, patients were receiving methylthioninium chloride outside its licensed indication.

Example of use of unlicensed medicines

Since June 2008, a licensed formulation of **thalidomide** has been available for treatment of multiple myeloma. Prescribers should consider use of this licensed thalidomide product first. Use of the licensed thalidomide product is important because pregnancy-prevention measures are linked to the prescription and dispensing of the authorised formulation, but not to those that are unlicensed.

Advice for prescribers:

Consider...

- Before prescribing an unlicensed medicine, be satisfied that an alternative, licensed medicine would not meet the patient's needs
- Before prescribing a medicine off-label, be satisfied that such use would better serve the patient's needs than an appropriately licensed alternative
- Before prescribing an unlicensed medicine or using a medicine off-label:
 - Be satisfied that there is a sufficient evidence base and/or experience of using the medicine to show its safety and efficacy
 - Take responsibility for prescribing the medicine and for overseeing the patient's care, including monitoring and follow-up
 - Record the medicine prescribed and, where common practice is not being followed, the reasons for prescribing this medicine; you may wish to record that you have discussed the issue with the patient

Communicate: best practice is that...

- You give patients, or those authorising treatment on their behalf, sufficient information about the proposed treatment, including known serious or common adverse reactions, to enable them to make an informed decision
- Where current practice supports the use of a medicine outside the terms of its licence, it may not be necessary to draw attention to the licence when seeking consent. However, it is good practice to give as much information as patients or carers require or which they may see as relevant
- You explain the reasons for prescribing a medicine off-label or prescribing an unlicensed medicine where there is little evidence to support its use, or where the use of a medicine is innovative

Report suspected adverse reactions...

- Healthcare professionals have a responsibility to help monitor the safety of medicines in clinical use through submission of suspected adverse drug reactions to the MHRA and CHM via the Yellow Card Scheme (see www.yellowcard.gov.uk). Such reporting is equally important for unlicensed medicines or those used off-label as for those that are licensed

Hot topics *continued*

Over-the-counter cough and cold medicines for children

The Commission on Human Medicines (CHM) has advised on measures to improve the safe use of cough and cold medicines for children under 12 years. This follows a thorough review by the MHRA of the benefits and possible risks of over-the-counter (OTC) cough and cold medicines for children under 12 years.

OTC cough and cold medicines containing the following active ingredients are affected by the advice: **antitussives** (dextromethorphan and pholcodine); **expectorants** (guaifenesin and ipecacuanha); **nasal decongestants** (ephedrine, oxymetazoline, phenylephrine, pseudoephedrine, and xylometazoline); and **antihistamines** (brompheniramine, chlorphenamine, diphenhydramine, doxylamine, promethazine, and triprolidine).

Overall these measures include changes to age ranges, introduces new advice on labelling, introduces child-resistant packaging (to help prevent overdoses), and recommends research into how effective the medicines are in children over 6 years.

Colds and coughs occur frequently in children but they are self-limiting and rarely harmful if left untreated. Moreover, many medicines given to children have not been properly studied in this population. Specific paediatric studies are needed because of differences between adults and children in drug handling or drug effects, which may lead to different dose requirements.

OTC cold and cough remedies were introduced when the requirement to demonstrate safety and efficacy was less robust compared to today's standards. However, over the years, the products have raised no special concern about safety.

The MHRA is working hard to improve the availability of high-quality, ethically researched and properly authorised medicines for children: see <http://www.mhra.gov.uk/Howweregulate/Medicines/Medicinesforchildren/index.htm> and Drug Safety Update January 2009, p 7; www.mhra.gov.uk/mhra/drugsafetyupdate

Key information:

- Cough and cold remedies containing the above ingredients should no longer be used in children under 6 years as the balance of benefits and risk has not been shown to be favourable
- Products for children from 6 to 12 years will continue to be available in pharmacies where advice can be given
- Medicines to treat cough and colds in older children (6 to 12 years) can be considered supplementary to basic principles of best care
- Some combinations (such as cough suppressants and expectorants) are being phased out
- All liquid products containing these ingredients will in future be in a child resistant container

Timing

Newly packaged products reflecting the above advice will start to be introduced to pharmacies later this year in time for the 2009/10 winter cough and cold season. In the meantime medicines with the older labelling will continue to be available and can be supplied for use by older children and adults. Immediate withdrawal of products with older labelling is not necessary because of the absence of a safety issue.

Products currently authorised with General Sales List (GSL) legal status may continue to be sold on open shelves and remain available through other retail outlets, such as supermarkets, until the new packaging reflecting Pharmacy (P) legal status becomes available. We expect the change to be complete by March 2010.

Hot topics *continued*

Further information is at
<http://www.mhra.gov.uk/Safetyinformation/Safetywarningsalertsandrecalls/Safetywarningsandmessagesformedicines/CON038908>. This webpage contains a letter for healthcare professionals, annex 2 of which has an extract of "Birth to 5".

CHM conclusions:

- There is no robust evidence that cold and cough medicines containing the above ingredients work. Given that there have been some reports of harm with these ingredients, the risks of cough and cold medicines containing them outweigh the benefits
- For children aged over 6 years, the risk from these ingredients is reduced because: they suffer from cough and cold less frequently and consequently require medicines less often; with increased age and size, the risk of toxicity is lower; and they can say if the medicine is working. For these reasons cold and cough medicines containing the above ingredients can continue to be available for these older children, but only through pharmacies where advice can be given
- Further research is required on how effective these products are in children over 6 years

Helpful advice for parents and carers on the basic principles of best care for children of all ages with coughs and colds can be found in the Department of Health's book "Birth to 5". Key aspects of this advice will be reflected in new Patient Information Leaflets accompanying all licensed products containing the active substances included in the review.

Other information from the MHRA

Patient Information Leaflet of the month: Proctofoam HC

Patient information leaflets (PILs) are improving in quality as a result of new legal obligations on manufacturers to test the documents with potential patients. Testing makes sure that the presentation of the information enables patients to find and understand key messages for safe use about the medicine within the PIL and thereby enables them to use the medicine safely and effectively. To promote this new initiative, we are publishing a series of examples of best practice on our website. The latest in the series is for **Proctofoam HC**, which contains pramocaine hydrochloride and hydrocortisone acetate. This medicine is a rectal foam indicated for the relief of symptoms of discomfort and pain associated with non-infective anal or perianal conditions. The leaflet includes risk-communication tools and diagrams, which in testing patients found helpful.

See
[http://www.mhra.gov.uk/Howweregulate/Medicines/Labelpatientinformationleafletsandpackaging/Patientinformationleaflet\(PIL\)ofthemonth/index.htm](http://www.mhra.gov.uk/Howweregulate/Medicines/Labelpatientinformationleafletsandpackaging/Patientinformationleaflet(PIL)ofthemonth/index.htm)

MHRA–NICE London study day for doctors in training

To discover how critical advice from MHRA and NICE can affect your day-to-day practice, why not register for a free study day arranged specially for doctors at the start of their career?

For details, visit
<http://www.mhra.gov.uk/ConferencesLearningCentre/Conferences/CON038859>

New MHRA webpage resource for pharmacists

We have launched a webpage resource for pharmacists, which includes information and advice on: interactions with patients; reporting of adverse events; and current topics of interest for medicines and medical equipment. Why not save this webpage as a favourite to your PC?

See
<http://www.mhra.gov.uk/Safetyinformation/Healthcareproviders/Pharmacy/index.htm>

Read more about the Commission on Human Medicines, including summaries of minutes from meetings, at

<http://www.mhra.gov.uk/mhra/CommissiononHumanMedicines>

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