Drug Safety Update

MHRA

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**

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Contents

Click on text to go to page

Antipsychotic medicines may be associated with an increased risk of venous thromboembolic events—read further information on p 2.

Also this month, as summer approaches we would like to remind you about the risk of photosensitivity reactions associated with topical ketoprofen gels (p 6).

Please also note new advice from the Commission on Human Medicines, which recommends that topical oral salicylate-containing products should be contraindicated in those younger than age 16 years in line with oral salicylate-containing preparations. These topical products are no longer indicated for pain associated with infant teething, orthodontic devices, cold sores, or mouth ulcers in this age-group. Pages 4 and 5 outline the reasons for this decision, based on the risk of salicylate toxicity in children if these products are overused.

To raise awareness of counterfeit medication and its dangers, the MHRA and the Royal Pharmaceutical Society of Great Britain have produced a leaflet for patients, which pharmacies are asked to distribute in patients' prescription bags as a pilot scheme. This campaign complements guidance for professionals issued earlier this year. Find out more on p 9 on the steps we continue to take to safeguard the public from counterfeit medicines.

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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.

Drug safety advice

Antipsychotics: risk of venous thromboembolic events

Keywords: antipsychotics, atypical, conventional (typical), deep vein thrombosis, pulmonary embolism, venous thromboembolic events, VTE

Antipsychotic use may be associated with an increased risk of venous thromboembolic events

A possible relation between use of antipsychotic medicines and venous thromboembolic events (VTE) was first suggested about five decades ago, after the introduction of phenothiazines. Since then, case reports of VTE have been received periodically through the Yellow Card Scheme and further studies have been completed that investigated this issue.[1,2]

A Europe-wide review of UK Yellow Card data and worldwide published epidemiological studies on antipsychotics and VTE has concluded that an increase in risk of VTE cannot be excluded.

1 Zornberg GL, Jick H. *Lancet* 2000; **356:** 1219–23.

2 Liperoti R, et al. *Arch Intern Med* 2005; **165:** 2677–82.

Yellow Card data

Many of the cases reported to us via the Yellow Card Scheme were potentially confounded by other risk factors or contained limited information to allow a clear causal relation to be established for antipsychotics and risk of VTE. Some of the known side effects of antipsychotics (eg, sedation, weight gain) are known risk factors for VTE, and a direct or indirect causal association between antipsychotic use and VTE could not be excluded.

Yellow Card Scheme: www.yellowcard.gov.uk

Published epidemiological data

Information from the literature is limited by a lack of randomised controlled trial data and by heterogeneity among the available observational studies. However, despite these limitations, all of the published studies to June 2008 conclude that there is an increased risk of VTE with exposure to antipsychotics.[1,2]

Product information for healthcare professionals and patients for all antipsychotics will be updated across the EU to include information about this risk. Product information for the antipsychotics clozapine, olanzapine, and aripiprazole already contains a warning about this risk.

Advice for healthcare professionals:

- Antipsychotic use may be associated with an increased risk of VTE
- At present there are insufficient data available to determine any difference in risk between atypical and conventional antipsychotics, or between individual drugs
- All possible risk factors for VTE should be identified before and during antipsychotic treatment and preventive measures undertaken

Further information is available in an MHRA assessment report available at http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Product-specificinformationandadvice/Antipsychoticdrugs/index.htm

Chloral hydrate (Welldorm) and Triclofos: not first-line options for insomnia

Keywords: Chloral hydrate, Welldorm, Triclofos, insomnia

Chloral hydrate and Triclofos are not first-line options for insomnia

Chloral hydrate is an older drug which retains some limited clinical usage. The licensed products in the UK are Welldorm elixir (containing chloral hydrate) and Welldorm tablets (containing a precursor, chloral betaine). Triclofos is a closely related drug, which is metabolised in the liver to the same active metabolite as that formed from chloral. All three products have been licensed for many years for short-term treatment of insomnia.

Product information for these medicines has recently been changed to reflect current clinical practice where they are not first-line options for insomnia. The licensed indications have been amended to the short-term treatment of severe insomnia which is interfering with normal daily life and where other therapies have failed, as an adjunct to non-pharmacological therapies.

The use of hypnotics in children and adolescents is not generally recommended, and if used should be under the supervision of a specialist. Welldorm tablets and Triclofos are not licensed for use in children. Welldorm elixir is licensed for use in adults and in children age 2 years or older. Treatment in children should be as an adjunct to behavioural therapy and sleep-hygiene management, and should not usually exceed 2 weeks.

For Triclofos Summary of Product Characteristics see www.emc.medicines.org.uk; for Welldorm Summary of Product Characteristics see www.alphashow.co.uk/products.html

The Summaries of Product Characteristics and patient leaflets are available for reference, and should be consulted for details of correct dose and other safety information.

See Drug Safety Update April 2009, p 6; www.mhra.gov.uk/mhra/drugsafetyupdate

We are aware that chloral hydrate is being used for sedation in children, for example in intensive care units and before diagnostic procedures, whether as off-label use of licensed products or unlicensed medicines. General guidance on prescribers' responsibilities when using a medicine off-label or using an unlicensed medicine has been published recently in Drug Safety Update.

Advice for healthcare professionals:

- Welldorm and Triclofos are indicated only for the short-term treatment of severe insomnia which is interfering with normal daily life and where other therapies have failed, as an adjunct to non-pharmacological therapies
- The use of hypnotics in children and adolescents is not generally recommended, and if used should be under the supervision of a specialist. Welldorm elixir can be used in children aged 2 years or older as an adjunct to behavioural therapy and sleep-hygiene management, usually for less than 2 weeks.

Oral salicylate gels: not for use in those younger than age 16 years

Keywords: oral salicylate gel, Reye's syndrome, salicylate toxicity, Bonjela, teething, orthodontic pain, cold sores, mouth ulcers

Topical oral salicylate gels are no longer indicated in those younger than age 16 years for pain associated with infant teething, orthodontic devices, cold sores, or mouth ulcers

The Commission on Human Medicines (CHM) has recommended that topical oral pain-relief products that contain salicylate salts should be contraindicated in those younger than age 16 years. This decision followed an in-depth review of these products, which was triggered by the publication of a report of a suspected case of Reye's syndrome associated with the use of an oral gel that contained choline salicylate in a 20-month-old child.[1]

Case details[1]

The child presented with a 1-day history of severe vomiting, lethargy, and photophobia after receiving one tube a day of a teething gel that contained choline salicylate. Investigations revealed a raised white-cell count, low blood glucose, and raised transaminases, but serum ammonia, coagulation, and urine toxicology were normal. The authors diagnosed Reye's syndrome after exclusion of metabolic disorders and because the systemic salicylate concentration was only just above the therapeutic range.

Salicylate toxicity

Serum salicylate levels, however, reflect a complicated, and to some extent unpredictable, combination of factors and are therefore considered a poor indicator of salicylate toxicity. Critical among these factors are: the saturation of hepatic enzymatic metabolism after chronic (ie, >2 days') ingestion;[2] changes in binding to plasma proteins; and movement of salicylate into tissues, which occurs mainly during metabolic acidosis. These factors result in an increase in the plasma salicylate half-life from 2–4·5 hours to 18–36 hours.[3] Given that the salicylate level was not measured until 24 hours after admission in the current case,[1] salicylate levels could have been considerably higher at the onset of symptoms.

Chronic toxicity has been reported after doses of 100 mg/kg per day for 2 days or longer.[4] Under conditions of chronic toxicity, children (particularly those younger than age 4 years) are more likely to develop serious complications such as hypoglycaemia and metabolic acidosis,[5] and seem particularly susceptible to the hepatotoxicity of salicylate.[6–9] In this case,[1] the child received one tube of teething gel a day for an unspecified time. A tube of Bonjela (15 g) contains 1·31 g choline salicylate (equivalent to approximately 930 mg aspirin). Thus, in a child who weighs 10 kg, this equates to 93 mg/kg aspirin per day.

Reye's syndrome is usually diagnosed in a child younger than age 16 years with unexplained non-inflammatory encephalopathy and one or more of:

- Serum hepatic transaminases increased ≥3-times upper limit of normal
- Plasma ammonia concentration increased ≥3-times upper limit of normal
- Hepatic panlobular microvesicular fatty infiltration

In addition, there should be no other reasonable explanation for the cerebral or hepatic disorders.

1 Oman TK, et al. *BMJ* 2008; **336:** 1376.

2 Gibson T, et al. *Br J Clin Pharm* 1975; **8:** 233–38.

3 Done AK. *Pediatrics* 1960; **26:** 800–07.

4 Temple AR. *Arch Intern Med* 1981; **141** (3 spec no): 364–69.

5 Winters RW, et al. *Pediatrics* 1959: **23:** 260–85.

6 Prescott LF. *Br J Clin Pharmacol* 1980; **10** (suppl): 373S–79S.

7 Rich RR, Johnson JS. *Arthritis Rheum* 1973; **16:** 1–9.

8 Athreya BH, et al. *Arthritis Rheum* 1975; **19:** 347–53.

9 Bernstein BH, et al. *Am J Dis Child* 1977; **131:** 659–63.

Thus, it would be atypical in a case of Reye's syndrome for plasma ammonia to be normal in the presence of raised transaminases. The child was young for classic Reye's syndrome, the median age of which is thought to be 6–7 years.

MHRA conclusions and CHM advice

We conclude that the clinical features in this patient[1] are more consistent with salicylate toxicity than with Reye's syndrome. Our assessment is based on the fact that all of the diagnostic criteria for Reye's syndrome were not met, and the child had received a significant dose of salicylate (equivalent to 93 mg/kg aspirin per day) through the excessive use of the topical preparation. Irrespective of the diagnosis, it is clear that a choline salicylate gel, if applied chronically and excessively, can result in systemic levels of salicylate of at least therapeutic levels. Given that no information is available as to the threshold concentration of salicylate required to precipitate Reye's syndrome, there is a theoretical risk that oral gels that contain choline salicylate, if used in excess, could increase the risk of Reye's syndrome.

On the basis of this evidence, while acknowledging that there is only a theoretical risk of Reye's syndrome with these oral gel products, CHM advised that any topical oral product that contains salicylate should be contraindicated in children younger than age 16 years in line with current advice on aspirin from the former Committee on the Safety of Medicines. An important factor in this decision is the availability of alternative treatment options to alleviate pain associated with infant teething, orthodontic braces, and mouth ulcers.

The MHRA has approved amendments to the product information for the relevant products and communicated the new advice to healthcare professionals and the general public.

Further information is available at http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON044014

Advice for healthcare professionals:

- Please advise parents and patients that those younger than age 16 years should use alternative treatments or products. There are several dental gels available which contain a local anaesthetic/mild antiseptic
- For infant teething, gentle pressure with something cool such as a chilled teething ring may help relieve teething pain
- For pain associated with orthodontic devices, salt water mouthwashes are recommended for sore areas. For discomfort arising from tooth movement, a paracetamol-based painkiller is recommended

Topical ketoprofen: reminder on risk of photosensitivity reactions

Keywords: Ketoprofen, photosensitivity, sunlight, sunlamps, sunbeds, ultraviolet, UV

Topical ketoprofen causes photosensitivity reactions, and users should avoid direct sunlight, ultraviolet rays, and sunbeds or sunlamps. Ketoprofen should be stopped and medical attention sought if skin reactions develop

Ketoprofen gels are licensed for the relief of the pain, inflammation, and stiffness associated with non-serious arthritis, sports injuries, sprains, and strains. They are available as both prescription-only medicines and in pharmacies.

Photosensitivity reactions with topical ketoprofen preparations have been recognised for several years, and there are warnings in the leaflet that accompanies every pack of medicine.

Healthcare professionals are reminded here about the potential for photosensitivity reactions in users of topical ketoprofen, and are asked to report, or encourage the user to report, any such reactions to the MHRA using a Yellow Card.

See
www.yellowcard.gov.uk

Advice for healthcare professionals:

Healthcare professionals, particularly pharmacists, are reminded to advise users to:

- Avoid direct sunlight, ultraviolet (UV) rays, sunlamps, and sunbeds while using topical ketoprofen, and to exercise caution for 2 weeks after stopping treatment
- Stop using ketoprofen gel and see a healthcare professional or go to hospital if they experience a skin reaction to sunlight, sunlamps, or sunbeds

Yellow Card Scheme update

The Yellow Card Scheme collects information on suspected adverse drug reactions in the UK. See www.yellowcard.gov.uk

The Black Triangle Scheme (▼ or ▼*)

Please report ALL suspected adverse reactions to Black Triangle drugs

When medicines come onto the market, we may have relatively limited information about their safety from clinical trials. These trials generally involve only relatively small numbers of patients who take the medicine for a relatively short time and will identify only the more common adverse effects of treatment. Only when large numbers of patients have taken a medicine are rare or long latency adverse effects identified. Therefore, effective surveillance after marketing is essential for the identification of rare adverse effects, and to ensure that appropriate action is taken.

New medicines are intensively monitored to ensure that any new safety hazards are identified promptly. The Commission on Human Medicines (CHM) and the MHRA encourages the reporting of all suspected reactions to newer drugs and vaccines, which are denoted by an inverted Black Triangle symbol (▼).
This symbol appears next to the name of a relevant product:

- In Drug Safety Update
- In the British National Formulary (BNF) and the Nurse Prescribers' Formulary (NPF)
- In the Monthly Index of Medical Specialities (MIMS)
- On the electronic Medicines Compendium (see http://emc.medicines.org.uk/)
- On advertising material

A Black Triangle symbol is assigned to any drug or vaccine that meets any of the following criteria:

- A new active substance or a biosimilar medicine
- A new combination of medicines or active substances
- A new route of administration
- A new drug-delivery system
- An established medicine which is to be used in a new patient population

For further information on biosimilar medicines, see Drug Safety Update February 2008, p 8; www.mhra.gov.uk/mhra/drugsafetyupdate

All similar biological medicines (biosimilars) have a Black Triangle symbol because although any such product has been developed to be similar to an existing biological product, it may not have an identical structure and thereby requires intensive monitoring of safety and efficacy.

Some well-established products may have the Black Triangle symbol reinstated—for instance if the product has been approved for use in a significantly new indication or in a new population. These products are denoted by an asterisk next to the Black Triangle (▼*). For example, the Black Triangle symbol has been reinstated for Cozaar▼* (losartan), specifically for the new indication of heart failure. Furthermore, Cancidas▼* (caspofungin) has had a Black Triangle reinstated after it was approved for use in children.

Yellow Card Scheme update *cont.*

The MHRA assesses the Black Triangle status of a product usually 2 years after marketing; however, there is no standard time for a product to retain Black Triangle status. The symbol is not removed until the safety of the drug is well established.

The CHM and the MHRA continue to monitor intensively all products with a Black Triangle symbol (▼). Healthcare professionals are asked to report **all** suspected adverse drug reactions to these products through the Yellow Card Scheme. The symbol ▼* highlights the importance of reporting suspected adverse reactions that are related to the reason for reinstating the Black Triangle to the drug (eg, use in a new indication or new patient population).
Such reporting helps us to:

- Confirm the benefit/risk profile that was established during clinical development
- Ensure that we identify previously unrecognised side effects as quickly as possible

The most recent list of products with a Black Triangle can be found on our website:
http://www.mhra.gov.uk/Safetyinformation/Howwemonitorthesafetyofproducts/Medicines/BlackTriangleproducts

For Black Triangle enquiries, please contact us at blacktriangle@mhra.gsi.gov.uk

Hot topic

Counterfeit medicines: patient guidance for distribution via pharmacies

Although the number of counterfeit medicines and medical devices entering the legitimate supply chain in the UK is small, pharmacists have an important role in helping prevent counterfeits reaching patients.

On ten occasions since 2004 we have recalled batches of medicines where counterfeits are likely to have reached patients through the legitimate supply chain, the last of which was in May 2009. On three other occasions in the past 2 years, counterfeit medical devices have been identified as being sold to UK consumers. Counterfeit medicines and medical devices are a health risk to patients because they are not subject to the rigorous quality standards required of legitimate manufacture.

See Stop press p 12 for news about counterfeit insulin pen needles.

See also http://www.mhra.gov.uk/Publications/Safetywarnings/Drugalerts/CON046565 for a drug alert for Seretide 250 Evohaler due to possible presence of counterfeit inhalers in the supply chain.

In recent years there has been an explosion of websites offering medicines for sale online, which has sparked much debate. The risk of obtaining substandard or counterfeit medication substantially increases when prescription-only products are purchased from unauthorised sources.

We are urging key stakeholders to assist in tackling these issues. Initiatives under way include awareness and providing 24-hour reporting hotlines.

Postcard guidance for patients

As part of a long-term public awareness campaign about counterfeit medication and its dangers, the MHRA and the Royal Pharmaceutical Society of Great Britain (RPSGB) have produced new guidance for patients, which is being issued through pharmacies. The pilot project (launched this May) involves every pharmacy in Great Britain distributing 50 copies of the guidance leaflets in patients' prescription bags.

The guidance has been developed in conjunction with patient groups. The postcard-size leaflet offers practical advice about the safest way to purchase medicines as well as explaining what counterfeit medications are, how to minimise the risk of buying them, and what to do if patients suspect that they have been sold or supplied counterfeits. It particularly focuses on the increased risks involved with obtaining medication online (see leaflet images).

Campaigning

See the cinema campaign online at www.realdanger.co.uk

We also collaborated with Pfizer and patient groups earlier this year to produce a hard-hitting cinema campaign designed to shock people into discussion about the dangers of obtaining medicine online. The footage shows a man regurgitating a rat (to reflect a previous discovery of rat poison in a fake medicine) after taking a pill ordered online.

Future MHRA campaigns will target consumers who may be at particular risk such as online shoppers, men's health forums, slimming clubs, and smoking-cessation bodies.

Professional guidance

See http://www.mhra.gov.uk/home/groups/ei/documents/websiteresources/con2033091.pdf

The new patient postcard complements updated guidance for pharmacists and dispensing doctors on counterfeit medicines that was published in February 2009 through collaboration between the MHRA, RPSGB, and Dispensing Doctors' Association.

This pharmacist guidance explains the background to the production and supply of counterfeit medicines, and offers advice on steps pharmacists should take if they encounter a suspected counterfeit medicine. These steps include reporting suspected illegal websites to the MHRA to help safeguard public health.

Email counterfeits@mhra.gsi.gov.uk; call 020 7084 2701 (24 hours); or report online at www.mhra.gov.uk

Similar guidance is being developed for doctors and nurses in association with the General Medical Council, British Medical Association, and Royal College of Nursing.

If a patient is concerned that they have a counterfeit medicine, then the pharmacist or dispensing doctor should make a record (noting if possible the patient's contact details, reason for the suspicion, product name, dose, batch number, and expiry date). They should then inform the MHRA immediately using the contact details above.

Healthcare professionals and the wider public can report suspected side-effects from a medicine that they suspect to be fake by completing a Yellow Card, available from www.mhra.gov.uk.

Online pharmacies

See http://www.healthcarerepublic.com/news/GP/898712/Exclusive-One-four-GPs-treats-reaction-online-medicine

The internet provides counterfeiters with easy access to consumers and markets. A recent GP newspaper survey has found that one in four GPs has treated patients for adverse reactions to medicines bought online.

See www.internetpharmacylogo.org

The RPSGB has developed an internet pharmacy logo to help the public identify a bona fide website that is operated by a registered pharmacy in Britain (see margin).

Further discussions between the MHRA and General Medical Council will look at ways to tighten current legislation and systems for the online supply of medicines. A particular focus will be online consultations, which have potential to be misused by patients who are unsuitable for a particular treatment, or by unscrupulous organisations that sell medicines without the involvement of a healthcare professional.

Further information

MHRA:

Buying medicines over the internet:

http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Adviceandinformationforconsumers/Buyingmedicinesoverthelnternet/index.htm

Counterfeit medicines and devices:

http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Adviceandinformationforconsumers/Counterfeitmedicinesanddevices/index.htm

Enforcing the law:

http://www.mhra.gov.uk/Howweregulate/Medicines/Enforcingthelaw/index.htm

Royal Pharmaceutical Society of Great Britain:
www.rpsgb.org

Dispensing Doctors' Association:
http://www.dispensingdoctor.org/

Stop press

Clopidogrel and proton pump inhibitors: possible interaction

Clopidogrel (Plavix) is indicated for the prevention of atherothrombotic events in patients who have had myocardial infarction or ischaemic stroke, or who have established peripheral arterial disease. Combined with aspirin, it may also be used to prevent atherothrombotic events in patients with acute coronary syndrome. **Proton pump inhibitors** (PPIs) are indicated for the treatment of oesophageal reflux disease, dyspepsia, or gastric ulcers.

Clopidogrel can cause gastrointestinal symptoms and is therefore frequently coprescribed with a PPI.

The EU Committee for Medicinal products for Human Use (CHMP) has reviewed the available evidence for an interaction between clopidogrel and PPIs. They conclude that the data support a clinically significant interaction that makes clopidogrel less effective when given with these medicines. Therefore, concomitant use of a PPI with clopidogrel is not recommended unless considered essential. Further information will be provided in the next (July 2009) issue of Drug Safety Update.

For further information see
http://www.emea.europa.eu

Advice for healthcare professionals:

- The need for PPI therapy in patients who are also taking clopidogrel should be reviewed at their next appointment: only use these medicines concomitantly when essential
- Prescribe PPIs strictly in line with their licensed indications
- Check that patients who are taking clopidogrel are not buying over-the-counter omeprazole

Erlotinib: new safety information

Erlotinib (Tarceva▼) is a treatment for patients with locally advanced or metastatic non-small-cell lung cancer, and for patients with metastatic pancreatic cancer (in combination with gemcitabine).

As part of continued intensive monitoring of this medicine, new safety information is available about the following risks:

- **Gastrointestinal perforation:** there have been reports of gastrointestinal perforation, and patients are at increased risk. Those who are receiving concomitant antiangiogenic agents, corticosteroids, non-steroidal anti-inflammatory drugs, or taxane-based chemotherapy, or who have a history of peptic ulceration or diverticular disease, are at increased risk. Erlotinib should be permanently discontinued in patients who develop gastrointestinal perforation
- **Bullous and exfoliative skin disorders:** bullous, blistering, and exfoliative skin conditions have been reported, including very rare cases suggestive of Stevens-Johnson syndrome or toxic epidermal necrolysis, some of which were fatal. Erlotinib should be interrupted or discontinued if a patient develops severe bullous, blistering, or exfoliating conditions

Stop press *cont.*

- **Ocular disorders:** very rare cases of corneal perforation or ulceration have been reported during use. Other ocular disorders including abnormal eyelash growth, keratoconjunctivitis sicca, or keratitis have been observed, which are risk factors for corneal perforation or ulceration. Erlotinib should be interrupted or discontinued if patients present with acute or worsening ocular disorders such as eye pain

See letter for healthcare professionals sent May 2009 at http://www.mhra.gov.uk/Safetyinformation/Safetywarningsalertsandrecalls/Safetywarningsandmessagesformedicines/Monthlylistsofinformationforhealthcareprofessionalsonthesafetyofmedicines/index.htm

Please continue to report suspected adverse reactions to erlotinib on a Yellow Card at www.yellowcard.gov.uk

Counterfeit insulin pen Novofine needles: vigilance needed for lot number 08J02S

The MHRA has identified a batch of **counterfeit Novofine needles for insulin pens** on the UK market. There is no assurance that these counterfeit needles have been manufactured to appropriate standards, and the risks posed to users include adverse reactions to the manufacturing materials, pain, discomfort, infection, and difficulty attaching the needle to the insulin injection pen.

See http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON041474

A medical device alert has been issued, providing details of how to identify these counterfeits.

Advice for healthcare professionals who manage patients who use or supply these needles:

- Do not supply needles with **lot number 08J02S**
- Quarantine affected needles from your current stock and contact Novo Nordisk for replacements
- Advise patients to return needles from lot number 08J02S to their pharmacist or to Novo Nordisk
- If a patient returns any Novofine needles with lot number 08J02S, supply the patient with a replacement and contact Novo Nordisk for replacement stock

See p 9

We continue to encourage healthcare professionals, patients, and the public to report all suspected cases of counterfeit or faulty medical devices to the MHRA via our website www.mhra.gov.uk

Stop press *cont.*

Lancing devices for blood-glucose monitoring

We continue to receive reports where transmission of hepatitis B has been linked to the use of the wrong type of lancing device to obtain capillary blood samples for analysis of blood glucose in those with diabetes. We have issued four medical device alerts and a poster on this topic in the past 5 years.

In the reports, lancing devices intended for self-testing by an individual have been used by healthcarers or care workers to take samples from more than one patient. Although the lancet is disposed of after every use, the end cap—which can become contaminated with blood—is not, and is therefore a potential source of cross-infection between patients. These lancing devices for self-testing by individuals are commonly supplied by manufacturers with glucose meters in blood-glucose monitoring kits.

All those involved in the prescription, supply, and use of blood-glucose monitoring kits should be aware that the lancing devices supplied with the kits are usually only safe for use by one person for self-testing. In settings where there is more than one patient, disposable single-use lancing devices where the entire unit is disposed of after use (a range is available on prescription), or non-disposable lancing devices which are designed and intended for use on more than one patient where the whole end of the lancing device is disposed of after use (available separately from meter manufacturers) should be used.

If in doubt about whether you are prescribing, supplying, or using the correct type of lancing device, further information can be obtained from the NHS PASA Buyers' Guide – Lancing Systems CEP 07025.

See
http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON020531
http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON2025400
http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON2022643
http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON008507
http://www.mhra.gov.uk/Publications/Postersandleaflets/CON046458

See
http://www.pasa.nhs.uk/PASAWeb/NHSprocurement/CEP/CEPproducts/CEP+catalogue.htm

Other information from the MHRA

Patient Information Leaflet of the month: Skelid for Paget's disease

Access PIL of the month at http://www.mhra.gov.uk/Howweregulate/Medicines/Labelspatientinformationleaflets andpackaging/Patientinformationleaflet(PIL) ofthemonth/index.htm

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 initiative, we are publishing a series of examples of best practice on our website. The latest in the series is for **Skelid**, which contains **tiludronic acid** and is indicated for the treatment of Paget's disease. The leaflet includes information about the benefits of this medicine, explaining how it works in this condition, which in testing patients found helpful.

Medical devices: practice guidance

Download our guidance on medical devices in practice for healthcare professionals and social-care professionals by visiting our website at http://www.mhra.gov.uk/Publications/Postersandleaflets/CON041487. This guidance includes a reference sheet for pharmacists, which has been produced in conjunction with the Royal Pharmaceutical Society of Great Britain.

Read more about the Commission on Human Medicines, including summaries of minutes from meetings, at www.mhra.gov.uk/Committees/Medicinesadvisory bodies/CommissiononHumanMedicines

Sign up to receive an email alert when a new issue is published: email registration@mhradrugsafety.org.uk

Report a suspected adverse drug reaction at www.yellowcard.gov.uk