



## CAUTION IN USE ALERT

### Clexane syringes — use of contaminated stock

Some batches of Clexane (enoxaparin sodium; Sanofi-Aventis) prefilled syringes containing low levels of over-sulphated chondroitin sulphate (OSCS) have been distributed in the UK over a period of four to six weeks. The Medicines and Healthcare products Regulatory Agency believes there is no evidence that these low levels of OSCS have led to adverse reactions. It adds that withdrawal of the contaminated Clexane products could lead to a shortage of low molecular weight heparins.

As a result, the Commission on Human Medicines has considered the matter and has recommended the continued supply of this product despite the low-level contamination. The following advice has been issued, covering both UK and parallel-imported stock:

- Enoxaparin is a very important therapy and it is essential that patients continue to receive it as prescribed by their doctor.
- As there is no evidence of any specific risks, and to maintain supplies, product on the UK market should continue to be used.
- Purely as a precaution, intravenous and arterial administration of enoxaparin should be avoided if possible. If given by these routes, suitable emergency treatment should be available and patients should be closely observed for signs of possible hypotensive or allergic reactions.

Healthcare professionals and patients are requested to report adverse reactions resulting from the use of any heparin or Clexane products via the yellow card scheme ([www.yellowcard.gov.uk](http://www.yellowcard.gov.uk)). Medical information is available from Sanofi-Aventis on 0800 281973.

It is expected that new and uncontaminated Clexane stock will become available from June 2008.

## SPC CHANGES

### Corticosteroids

The summaries of product characteristics for Medrone (methylprednisolone; Pharmacia) tablets, Solu-Medrone (methylprednisolone sodium succinate; Pharmacia) injections and Solu-Cortef (hydrocortisone sodium succinate; Pharmacia) injection have been updated to include a warning about potential psychiatric side effects occurring with systemic steroids.

### Hepsera

In lamivudine-resistant patients, Hepsera (adefovir dipivoxil; Gilead) should be used in combination with lamivudine, not as monotherapy, to reduce the risk of resistance, the summary of product characteristics for Hepsera now states. It adds: "In order to reduce the risk of resistance in patients receiving adefovir dipivoxil monotherapy, a modification of treatment should be considered if serum HBV

DNA remains above 1,000 copies/ml at or beyond one year of treatment." The SPC also warns that resistance to Hepsera can result in viral load rebound, which could result in exacerbation of hepatitis B and, if hepatic function is reduced, lead to liver decompensation and mortality. Virological response should be monitored closely and if viral rebound occurs resistance testing should be performed. Renal failure, Fanconi syndrome, hypophosphatemia, proximal renal tubulopathy and associated myopathy and osteomalacia have been added to the list of undesirable effects (frequency not known) from post-marketing surveillance.

### Provigil

Serious rash requiring admission to hospital and discontinuation of treatment has been reported with the use of Provigil (modafinil; Cephalon), occurring one to five weeks after treatment initiation, the summary of product characteristics for Provigil now states. Isolated cases of serious rash have been reported after prolonged treatment (eg, three months), the SPC adds. It also says that patients with major anxiety should only receive treatment with Provigil in a specialist unit. Psychiatric adverse experiences, including suicidal ideation, have

been reported in patients treated with modafinil. In such circumstances, modafinil should be discontinued and not restarted. Caution should be exercised in administering modafinil to patients with a history of psychosis, depression or mania, the SPC says.

### Sandimmun

Patients on Sandimmun (ciclosporin; Novartis) concentrate for infusion should be warned to avoid excess ultraviolet light exposure in view of the potential risk of skin malignancy, the product's summary of product characteristics now says. The SPC also now states that renal function should be monitored with particular care in elderly patients and that caution should be exercised when co-administering lercanidipine with ciclosporin.

## PRESCRIPTION PRODUCTS

### Meningitec

Meningitec (meningococcal serogroup C oligosaccharide conjugate vaccine [adsorbed]; Wyeth) is now available in prefilled syringes. The 10 x 0.5ml vials are no longer available. Childhood immunisation programme supplies are available from Movianto UK on 0870 871 1891. Net price: 10 x 0.5ml prefilled syringe, £75. Legal category: POM.

### Pentasa

Pentasa 2g sachets (mesalazine prolonged release granules) are now available from Ferring Pharmaceuticals. Net price: 60 x 2g sachets, £72.05. Legal category: POM.

## DRUG TARIFF UPDATES

### Bisacodyl suppositories

The Department of Health and the National Assembly for Wales have agreed to allow "no cheaper stock obtainable" (NCSO) endorsements for bisacodyl suppositories 10mg for April prescriptions.

## RESOURCES

### SOPs for safety

The National Pharmacy Association has produced standard operating procedures and guidance notes for the safe dispensing of oral anti-cancer medicines in the community and for supply of paraffin-based skin products, following National

Patient Safety Agency rapid response reports on these topics earlier this year. Both resources are available from the members' area of the NPA website ([www.npa.co.uk](http://www.npa.co.uk)).

## APPOINTMENTS

### Nayantara Chotai

Nayantara Chotai, MRPharms, has been appointed pharmacy services development manager at Pharmaplus Ltd.

## FUTURE EVENTS

### IT interest group

Guild of Healthcare Pharmacists and United Kingdom Clinical Pharmacy Association joint IT Interest Group seminar, looking at progress on the NHS spine in England, IT developments in Wales and benefits of e-prescribing, Coventry, 4 June. Cost £90 (NHS employees, GHP/UKCPA/Unite union members), £140 (non-NHS, non-members). Further information from Jean Fairhurst on 01296 662209 (e-mail [jean.fairhurst@ntlworld.com](mailto:jean.fairhurst@ntlworld.com)).

### APTUK conference

Association of Pharmacy Technicians UK annual conference "On course", St Andrews, Fife, 5-8 June. Costs and further information from 07932 676485 or 01383 727360 (e-mail [oncourse2008@live.co.uk](mailto:oncourse2008@live.co.uk)) and via [www.aptuk.org](http://www.aptuk.org).

## CLARIFICATIONS

### Hydrocortisone tablets

Only generic hydrocortisone tablets 10mg and 20mg are available from Auden Mckenzie, not Hydrocortone-branded hydrocortisone tablets as stated in last week's *Journal* (p502).

## Contact us

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## Accessing SPCs

The summaries of product characteristics and patient information leaflets for medicines licensed in the UK are available via <http://emc.medicines.org.uk>.