

MEDICAL DEVICE ALERT

Makromed urine test strips

Makromed Manufacturing Ltd has recalled all models and batches of Makromed urine test strips (distributed in the UK by Sterilab Services) with expiry dates in 2007 and 2008 due to a potential for false negative results when testing for blood or ketones in urine. The product should not be used and all remaining stock should be quarantined. Details of batch numbers, and procedures for reporting the product and returning it for credit are available via the "Safety warnings, alerts and recalls" section of the Medicines and Healthcare products Regulatory Agency website (www.mhra.gov.uk). Enquiries can be made to Sterilab Services on 01423 523300.

SPC CHANGES

Aricept

The summary of product characteristics for Aricept (donepezil; Eisai) has been updated. The SPC now states the quantity of lactose in each film-coated tablet. Information about mortality in vascular dementia clinical trials has been added to the special warnings section. Diarrhoea, nausea and headache have been moved from "common" to "very common" in the table of undesirable effects. See SPC.

Celebrex

The summary of product characteristics for Celebrex (celecoxib; Pfizer) has been updated to include a new indication for symptomatic relief in the treatment of ankylosing spondylitis. The recommended dose for this indication is 200mg taken once, or in two divided doses, each day. In a few patients, with insufficient relief from symptoms, an increased dose of 400mg once, or in two divided doses, each day may increase efficacy, the SPC states. See SPC.

Emselex

The summary of product characteristics for Emselex (darifenacin; Novartis) has been

updated to include blurred vision and urinary retention as possible side effects. See SPC.

NeoRecormon

The summaries of product characteristics for NeoRecormon (epoetin beta; Roche) have been updated. The indications sections have been reworded and now say: "Treatment of symptomatic anaemia in adult patients with non-myeloid malignancies receiving chemotherapy". The administration sections now state that the weekly dose of NeoRecormon for all patients can be given as one injection per week or in divided doses three to seven times a week. The recommended initial dose is 30,000IU per week. See SPCs.

Neupogen

The summaries of product characteristics for Neupogen (filgrastim; Amgen) have been updated to include a precaution that the needle cover of the pre-filled syringe contains dry natural rubber (a derivative of latex), which may cause allergic reactions. The special warnings sections of the SPCs also state: "Increased haematopoietic activity of the bone marrow in response to growth factor therapy has been associated with transient positive bone-imaging findings. This should be considered when interpreting bone-imaging results." See SPCs.

Rapamune

The summary of product characteristics for Rapamune (sirolimus; Wyeth) now includes additional safety information. It states that the use of Rapamune, mycophenolate mofetil and corticosteroids, in combination with IL-2 receptor antibody induction, is not recommended in the *de novo* renal transplant setting. It now recommends periodic quantitative monitoring of urinary protein excretion. Nephrotic syndrome has been

added to the list of undesirable effects. See SPC.

Rivotril

The summary of product characteristics for Rivotril (clonazepam; Roche) has been updated to include new information on the treatment of overdose. See SPC.

Roaccutane

The summary of product characteristics for Roaccutane (isotretinoin; Roche) has been updated. Concurrent administration of Roaccutane with topical keratolytic or exfoliative anti-acne agents should be avoided as local irritation may increase, the SPC says. The SPC now includes a warning that patients who experience drowsiness, dizziness or visual disturbances should not drive or operate machinery. See SPC.

Tarceva

The summary of product characteristics for Tarceva (erlotinib; Roche) has been updated to include a new indication for treatment, in combination with gemcitabine, of patients with metastatic pancreatic cancer. The special warnings section of the SPC now includes information about rare cases of hepatic failure (including fatalities) reported during use of Tarceva. The SPC also includes new information about drug interactions. Alopecia is now included as a common adverse effect. See SPC.

Zonegran

The summary of product characteristics for Zonegran (zonisamide; Eisai) has been updated with new information on the use of Zonegran during pregnancy and the risk of birth defects. A warning about severe rash and Stevens-Johnson syndrome has been given greater prominence in the special warnings section. See SPC.

ANNOUNCEMENTS

Parlodel

The licence for Parlodel (bromocriptine, as mesilate) has been transferred from Novartis Pharmaceuticals to Meda Pharmaceuticals. Medical information is now available from Meda on 01748 828810.

Visudyne

The Committee for Medicinal Products for Human Use has

reviewed post-marketing data for Visudyne (verteporfin; Novartis) and has specified that its indication for "the treatment of patients with age-related macular degeneration with occult subfoveal choroidal neovascularisation with evidence of recent or ongoing disease progression" be deleted because the benefit-risk profile is no longer considered favourable.

DRUG TARIFF UPDATES

Bisacodyl

The Department of Health and the National Assembly for Wales have agreed to allow "no cheaper stock obtainable" (NCSO) endorsements for bisacodyl enteric-coated tablets 5mg for May prescriptions.

WANTS

Generics in Nicaragua

The British Consultancy Charitable Trust would like to hear from a pharmaceutical chemist interested in travelling to Nicaragua to advise on the production of generic drugs. All expenses would be paid. The assignment is likely to last a few weeks. Contact Gillie Green at assignments@bcct.org.uk.

FUTURE EVENTS

Information technology

Inaugural United Kingdom Clinical Pharmacy Association and Guild of Healthcare Pharmacists IT Interest Group joint seminar, entitled "The clinical application of information technology". 6 June, Coventry. Cost £90 (members), £110 (non-member NHS employees), £140 (others). Further information from jean.fairhurst@ntlworld.com.

Medication safety

The United Kingdom Clinical Pharmacy Association is offering a reduced attendance fee of £58 for members to attend its Quality and Risk Management Group study day "Whose role is it anyway?", 7 June, Leicester. Further information on 0116 2776999 (e-mail admin@ukcpa.com).

Urology study day

United Kingdom Clinical Pharmacy Association Surgery and Theatres Group study day on urology, 26 June, London. Cost £115 (members), £180 (non-members). Further information and bookings on 0116 2776999 (e-mail admin@ukcpa.com).

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