



RECALLED PRODUCTS

Scheriproct ointment 30g

Intendis has recalled the following batches of Scheriproct (prednisolone hexanoate, cinchocaine hydrochloride) ointment 30g because of degradation of the local anaesthetic component.

Batch number	Expiry date	Pack size	First distributed
74093A	30 November 2012	30g tube	19 March 2008
81004A	31 January 2013	30g tube	23 May 2008

Recipients are requested to quarantine any remaining stock and return it to their supplier for credit. Enquiries can be directed to Valeant Pharmaceuticals, the UK distributor (medical information on 01748 828799; customer services on 01256 374808).

NEW MEDICINES

Toviaz

COMPOSITION: Fesoterodine fumarate.

PRESENTATION: Prolonged-release tablets.

CLASS: Urinary antispasmodic.

INDICATIONS: Treatment of the symptoms (increased urinary frequency, urgency or urgency incontinence) that may occur in patients with overactive bladder syndrome.

DOSAGE: Initially 4mg once daily. The dose may be increased to 8mg once daily based upon individual response. The maximum daily dose is 8mg.

CONTRAINDICATIONS:

Hypersensitivity to the active substance, or to peanut, soya or any of the excipients; urinary retention; gastric retention; uncontrolled narrow angle glaucoma; myasthenia gravis; severe hepatic impairment; concomitant use of potent cytochrome P450 CYP3A4 inhibitors in subjects with moderate to severe hepatic or renal impairment; severe ulcerative colitis; toxic megacolon.

PRECAUTIONS: Patients should be evaluated for efficacy of treatment after eight weeks. For patients with normal renal and hepatic function taking potent inhibitors of CYP3A4 concomitantly, the maximum dose of Toviaz should be 4mg daily. For patients taking moderate inhibitors of CYP3A4 concomitantly with Toviaz, a dose increase to 8mg should be preceded by evaluation of the patient's individual response. Dosing recommendations for patients with degrees of renal or hepatic impairment receiving or not receiving concomitant CYP3A4 inhibitors are included in the summary of product characteristics for Toviaz. Caution is required when combining Toviaz with moderate or potent CYP3A4 inhibitors or potent CYP2D6

inhibitors. Toviaz should be used with caution for patients at risk of QT-interval prolongation and those with relevant pre-existing cardiac conditions. Caution should be exercised when treating patients with: clinically significant bladder outflow obstruction at risk of urinary retention; gastrointestinal obstruction (eg, pyloric stenosis); gastro-oesophageal reflux (or patients taking medicines that can cause or exacerbate oesophagitis); decreased gastrointestinal motility; autonomic neuropathy; controlled narrow-angle glaucoma. Co-administration of Toviaz with other antimuscarinic agents and medicines with anticholinergic properties could lead to more pronounced therapeutic and adverse effects. As with other antimuscarinic medicines, caution should be exercised with driving or using machines because of possible side effects such as blurred vision, dizziness and somnolence.

SIDE EFFECTS: Very common ($\geq 1/10$) dry mouth. Common ($\geq 1/100$ to $< 1/10$) dizziness, headache, dry eyes, dry throat, abdominal pain, diarrhoea, dyspepsia, constipation, nausea, dysuria, insomnia.

LEGAL CATEGORY: POM.

NET PRICE: 28 x 4mg, £29.03; 28 x 8mg, £29.03.

CONTACT DETAILS: Pfizer Ltd, Ramsgate Road, Sandwich, Kent CT13 9NJ.

ANNOUNCEMENTS

Neupro patches

Neupro (rotigotine; UCB Pharma) patches should now be refrigerated (2–8°C), following advice from the European Medicines Agency. The new storage conditions are intended to reduce occurrence of crystallisation of the active substance in the patch. UCB Pharma reports that it has not observed a change in the pattern of clinically relevant events, including

CAUTION IN USE ALERT

Clexane syringes

Further to alerts from the Medicines and Healthcare products Regulatory Agency (*PJ*, 3 May, p533, and *PJ*, 17 May, p588) about batches of Clexane (enoxaparin sodium; Sanofi-Aventis) pre-filled syringes contaminated with over-sulphated chondroitin sulphate (OSCS), the following advice has been issued:

- There is no evidence of any specific risks to pregnant women or the developing fetus from exposure to the levels of OSCS found in some enoxaparin batches. However, on a purely precautionary basis, use of affected batches should be avoided in pregnant women.
- Prescribers should continue to avoid administering enoxaparin via the intravenous (off-label) or arterial line routes.
- To address a temporary shortage of 150mg pre-filled syringes, prescribers should consider using enoxaparin multi-dose vials, a combination of lower dose strengths of pre-filled syringes or a suitable alternative product. Adequate training should be provided to patients who self-inject, to prevent administration error.

A letter to healthcare professionals from Sanofi-Aventis (dated 6 June), providing information about uncontaminated batches of 40mg syringes for pregnant patients and recommendations for administration of 150mg doses, is available from the "Safety warnings, alerts and recalls" section of the MHRA website (www.mhra.gov.uk).

lack of efficacy, that could be attributed to formation of crystals (which resemble snowflakes and may cover up to 40 per cent of the patch surface). UCB will be introducing refrigerated stock over the next few months; for a period,

beginning late June, the market will only be supplied with 2mg/24h and 4mg/24h patches. The company warns that patients should not stop using the Neupro patches abruptly and that patients' existing stock can be used in the interim.

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