NON-PRESCRIPTION MEDICINES 4e – UPDATES, NOVEMBER 2010 – MAY 2011

Chapter	Page	Heading/ subheading	Update info.	Date
6	33	Local decongestants/product presentation	Fenox spray discontinued.	March 2011
21	140	Treatment – nasal preparations	New subsection: Antihistamines/ azelastine. Having been withdrawn by its previous manufacturer, azelastine 0.1% nasal spray has been relaunched as Rhinolast Allergy nasal spray by Meda Pharmaceuticals. Azelastine is a second-generation antihistamine. It is a potent long-acting anti-allergic compound with marked H1-antagonist properties, but for intranasal use, and at the doses administered, has only local activity. It has been found to be as effective in controlling the symptoms of rhinitis as oral second generation antihistamines, but with conflicting results when compared to intranasal corticosteroids.[1] Twice-daily use is recommended. Intranasal azelastine is not licensed for OTC sale for use in children under 5 years, and caution is recommended for use in pregnant and breast-feeding women. The maximum recommended treatment period without medical supervision is one month. 1. Golden SJ, Craig TJ. Efficacy and safety of azelastine nasal spray for the treatment of allergic rhinitis. J Am Osteopath Assoc. 1999;99(7 Suppl):S7-12.	April 2011
23	159	Treatment – antacids/Additional ingredients – alginates/Products	Rennies Dual Action Tablets and Rennies Dual Action Liquid discontinued.	March 2011
23	167	Treatment – domperidone	Domperidone maleate tablets further licensed for supply without prescription for the relief of post-prandial symptoms of excessive fullness, nausea, epigastric bloating and belching, occasionally accompanied by epigastric discomfort and heartburn.	January 2011
33	218	Aspirin and ibuprofen/Formulation factors/Aspirin/Product examples	Aspro Clear tablets discontinued.	March 2011
33	223	Treatment with combination products/ new subheading: Ibuprofen/ paracetamol combination	Nuromol tablets (Reckitt Benckiser) is the first non-prescription analgesic that combines ibuprofen (200mg) and paracetamol (500mg). It is licensed for use in adults over 18 years, for the temporary relief of mild to moderate pain for the same range of indications as both ibuprofen and paracetamol individually. The dose is one or two tablets three times daily, with at least six hours between doses and a	March 2011

			maximum of six tablets in 24 hours. Contra-indications, side-effects and precautions are as for both ibuprofen and paracetamol. The manufacturer claims that the formulation allows both constituents to be released simultaneously and achieves in vitro dissolution much faster than standard formulations of paracetamol or ibuprofen. However, evidence published by the manufacturer appears to show that the time to achieve maximum analgesic effect does not differ significantly from that of other non-prescription analgesic combinations, although the maximum analgesic effect attained is greater.[1] Two studies have found that the combination product was significantly more effective than were comparable doses of ibuprofen or paracetamol alone in moderate to severe acute dental pain, and significantly more effective than placebo in providing sustained pain relief comparable or superior to other combination analgesics indicated for strong pain.[2,3] 1. Advertisement in *Chemist and Druggist*, 19 March 2011. 2. Mehlisch DR, Aspley S, Daniels SE, Southerden KA, Christensen KS. A single-tablet fixed-dose combination of racemic ibuprofen/paracetamol in the management of moderate to severe postoperative dental pain in adult and adolescent patients: a multicenter, two-stage, randomized, double-blind, parallel-group, placebo-controlled, factorial study. Clin Ther. 2010;32:1033-49. 3. Daniels SE, Goulder MA, Aspley S, Reader S. A randomised, five-parallel-group, placebo-controlled trial comparing the efficacy and tolerability of analgesic combinations including a novel single-tablet combination of ibuprofen/paracetamol for postoperative dental pain. Pain. 2011;152:632-42.	
33	228	Non-steroidal anti-inflammatory drugs/Product examples	New presentation: medicated plasters containing 140 mg diclofenac sodium reclassified from POM to P for the symptomatic treatment of pain in acute strains, sprains or bruises in the extremities for people over 15 years of age. Product: Algopain-eze (Ratiopharm).	February 2011
34	236	Treatment/products	Regaine 5% Foam introduced. Regaine for Men Regular Strength (2%) solution, Regaine for Men Gel (2%) – discontinued. Regaine Extra Strength (5%) solution –discontinued.	January 2011 February 2011
37	257	Treatment – nicotine replacement therapy/Delivery systems	New delivery system – oromucosal spray. Contains 1 mg nicotine in each 0.07 ml spray. The product is indicated to aid smokers wishing to quit or reduce prior to quitting, to assist smokers who are unwilling or unable to smoke, and as a safer alternative to smoking for smokers and those around them. It is licensed for use in adults and children over 12 years of age, and can be used by pregnant or breast	March 2011

			feeding women. Compared to nicotine gum or lozenges, absorption of nicotine from the mouth spray is more rapid and is claimed to result in a faster onset of relief of cravings and other symptoms. The manufacturers claim that the product relieves cravings in 60 seconds and is 47% more effective at helping smokers to quit compared to placebo at 4 weeks. To date, there appear to be no comparisons of efficacy in relation to other nicotine replacement delivery systems. Dosage: 1-2 sprays into the mouth when cigarettes would normally have been smoked or if cravings emerge. Normal frequency of dosage, 1-2 sprays every 30 minutes to one hour. Maximum dosage, 4 sprays per hour and 64 sprays in 24 hours. Product: Nicorette Quick Mist (McNeil).	
New section. Menorrhagia: Tranexamic acid	Menorrhagia has been defined as menstrual blood loss exceeding 80 mL per cycle. Approximately 10% of women of reproductive age have blood loss exceeding 80 mL and 5–15% of women are thought to be affected to such a degree that treatment should be considered. However, in practice menorrhagia is generally self-diagnosed through a woman's subjective assessment of blood loss. In January, 2011, tranexamic acid 500 mg film-coated tablets were marketed, licensed for non-prescription use for reduction of heavy menstrual bleeding (menorrhagia) over several cycles, in women with regular, 21–35 day cycles with no more than 3 days individual variability in cycle duration. **Mode of action** The fibrinolytic system contributes to the prevention of blood clots through conversion of an inactive plasma enzyme, plasminogen, to plasmin which has a fibrinolytic action. Women with menorrhagia have been found to have increased levels of plasminogen activators in the endometrium of the uterus compared to women with normal blood loss. Tranexamic acid is an antifibrinolytic agent that competitively inhibits the activation of plasminogen to plasmin and thus has an antifibrinolytic effect, but it is not thrombogenic. As a POM it is also indicated for preventing blood loss during surgical procedures. Tranexamic acid has been in use as a POM for over 40 years (in the UK since 1983) and has been available without prescription in Sweden since 1997; in that time treatment for menorrhagia corresponds to 3.2 million women years and a further 15 million patients have been treated for other indications. The risk of thromboembolic events in women taking the drug is considered to be no higher than that in fertile women generally. Also, there is no evidence that tranexamic acid increases the risk of thrombosis in women taking hormonal contraceptives **Dosage** 2 tablets 3 times daily for as long as is needed, to a maximum of 4 days. The dosage may be increased if there is very heavy menstrual bleeding, but a total dose of 4 g daily should not be exceeded. Treatment should not be initiated until menstrual bleeding has started. Patients should consult their doctor if menstrual bleeding is not reduced after three menstrual cycles. **Side-effects and contraindications** Side-effects are nausea, diarrhoea and vomiting, described as common (≥1/100 to <1/10); allergic skin reactions, uncommon (≥1/1,000 to <1/100).			

	Tranexamic acid is contraindicated in the following circumstances: mild to moderate renal insufficiency; hypersensitivity to tranexamic acid or any of the excipients; active thromboembolic disease, a previous thromboembolic event or a family history of thrombophilia; haematuria; irregular menstrual bleeding, patients using warfarin or other anticoagulants; women taking oral contraceptives. **Cautions** Women who are over the age of 45 years, who are obese and diabetic, who have polycystic ovary syndrome, who have a history of endometrial cancer in a first-degree relative, or who are receiving unopposed oestrogen or tamoxifen, should consult their doctor before purchasing tranexamic acid. Menorrhagia may be a symptom of endometrial cancer, ovarian cancer, endometriosis, fibroids, chronic pelvic inflammatory disease, thyroid disorders and blood clotting abnormalities. Pharmacists should therefore refer women seeking to buy tranexamic acid to their doctors if they report any of the following: irregular periods; bleeding between periods; bleeding after the menopause; pain during intercourse; bleeding after intercourse; premenstrual pain; pelvic pain; symptoms of thrombosis – pains or feelings of heaviness in the chest, unusual pains or swellings in the arms or legs; sudden shortness of breath; fainting; haemoptysis. Tranexamic acid passes into breast milk to a concentration of approximately one hundredth of the concentration in the maternal blood. An antifibrinolytic effect in the infant is unlikely, nevertheless breastfeeding women should consult their doctor before taking the drug. **Interactions** Tranexamic acid will counteract the thrombolytic effect of fibrinolytic preparations. **Products** Cyklo-f 500 mg tablets (Meda Pharmaceuticals, currently marketed as Boots Cyklo-f and available only from Boots stores); Femstrual 500 mg tablets (Manx Healthcare).