Book review

Handbook of extemporaneous preparation. Jackson M, Lowey A.

London: Pharmaceutical Press; 2010. 464 pages. Price $41.95.

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This book presents a thorough examination of some 50 oral liquids prepared extemporaneously from commercially available products, mostly tablets. Since the commercial availability of oral liquids is limited, and the world's population is ageing with concomitant swallowing difficulties, this resource offers a real advantage to both the prescriber and the pharmacist in the provision of quality oral liquids which can be safely administered to patients unable to swallow solid dosage forms such as tablets and capsules.

This book provides monographs for oral formulations commonly prepared in UK hospitals. Each monograph provides essential information such as: formula, method of preparation, risk assessment, stability, storage and references. The comprehensive list of references for each drug monograph, relating to stability data and in some cases bioavailability, provides the prescriber with evidence that a quality product is being prepared. The first section of the book also provides interesting insight into the appropriate standards with respect to personnel, equipment, documentation, procurements and monitoring required for extemporaneous dispensing.

Of particular use and unique to this text is the inclusion of a 'risk assessment' section in each monograph which addresses the clinical and technical risks associated with the extemporaneous preparation of each oral liquid. The attention of the health professional is drawn to the potential risks, for example formulation failure and calculation errors, associated with extemporaneous dispensing, and a checklist is also provided which will assist in managing this risk.

This book is not only a useful resource, but a valuable addition to the texts available on extemporaneous dispensing for those prescribers wanting quick access to suitable oral liquid alternatives when commercially available products are not available.

New drugs

Some of the views expressed in the following notes on newly approved products should be regarded as tentative, as there may be limited published data and little experience in Australia of their safety or efficacy. However, the Editorial Executive Committee believes that comments made in good faith at an early stage may still be of value. As a result of fuller experience, initial comments may need to be modified. The Committee is prepared to do this. Before new drugs are prescribed, the Committee believes it is important that full information is obtained either from the manufacturer's approved product information, a drug information centre or some other appropriate source.

Apixaban

Eliquis (Bristol Myers Squibb)

2.5 mg film-coated tablets

Approved indication: prevention of postoperative venous thrombosis

Australian Medicines Handbook section 7.1.4

Patients undergoing knee and hip surgery have a high incidence of venous thromboembolism postoperatively. Thromboprophylaxis reduces this risk and current recommendations include heparins (enoxaparin, dalteparin) and the factor Xa inhibitor, fondaparinux. Oral anticoagulants – dabigatran and rivaroxaban – are also available for this indication.

Apixaban is a reversible, direct inhibitor of clotting factor Xa with a similar action to rivaroxaban (Aust Prescr 2009;32:22-7). By blocking factor Xa, it decreases levels of thrombin.

The efficacy of oral apixaban has been compared to subcutaneous enoxaparin for thromboprophylaxis after knee replacement (ADVANCE-1 and -2)[1,2] and hip replacement (ADVANCE-3).[3] Apixaban was started 12–24 hours after surgery and continued for 10–14 days in the knee trials and for 35 days in the hip trial. The primary outcome was the same in all of the trials and was a composite of deep vein thrombosis (symptomatic or asymptomatic), non-fatal pulmonary embolism, or death from any cause during treatment. Deep vein thrombosis was assessed using bilateral venography.

In ADVANCE-1, apixaban 2.5 mg (twice daily) failed to meet non-inferiority criteria compared to enoxaparin 30 mg (every 12 hours), despite the primary outcome occurring at similar rates (9% vs 8.8%). The enoxaparin dose used in this trial was different from the standard dose used in Australia – enoxaparin 40 mg once daily.[4] Although the number of deep vein thromboses was similar between groups, pulmonary emboli were more common with apixaban (16/1599 vs 7/1596).[1]

In ADVANCE-2, apixaban 2.5 mg (twice daily) was non-inferior to enoxaparin 40 mg once daily. The primary outcome occurred