

encapsulate

Welcome to 'encapsulate'

The second edition of 'encapsulate' highlights concerning side effects of bisphosphonates & opioid analgesic skin patches. We have also included an update on legislative requirements regarding Schedule 8 Drugs.

You can obtain further copies of 'encapsulate' via our website - www.slade.net.au. If you have any comments or wish to suggest a topic for our next issue please e-mail us - marketing@slade.net.au.

Bisphosphonates and Osteonecrosis of the Jaw

Bisphosphonates act by inhibiting the resorption of bone. Indications include osteitis deformans (Paget's disease of the bone); the prevention and treatment of osteoporosis; bony metastases of cancers (with or without hypercalcaemia); multiple myeloma; and other conditions exhibiting bone fragility. They can be administered orally or by intravenous injection.

For several years bisphosphonates have been associated with a rare but serious, and difficult to treat, adverse effect called osteonecrosis of the jaw (ONJ).

Health professionals should be aware of the presentation of clinical features of ONJ, which include altered local sensation (hyperaesthesia or numbness), maxillofacial pain, "toothache", denture sore spots, loose teeth, exposed bone in the oral cavity, impaired healing, recurrent or persistent soft tissue infection in the oral cavity and marked halitosis. The on-set can be from months to years after commencing bisphosphonate therapy.

Factors that increase the risk of developing ONJ include use of the intravenous forms of bisphosphonates, pre-existing poor dental hygiene and dental procedures conducted whilst using and for a period after using a bisphosphonate drug.

The Therapeutic Goods Association (TGA), in association with the Adverse Drug Reactions Advisory Committee (ADRAC) and Australian Drug Evaluation Committee (ADEC) have released numerous publications drawing attention to the association of bisphosphonates and ONJ, and offering advice on management strategies.

Health professionals involved in the prescribing, dispensing and administration of bisphosphonate drugs are encouraged to:

- Consider a dental referral for the patient before starting treatment, especially for those at increased risk, e.g. the elderly
- Reinforce the importance of good oral hygiene
- Inform their patients of the symptoms of osteonecrosis of the jaw.
- Advise their patients to notify their dentist they have commenced bisphosphonate treatment.

Analgesic Skin Patch Misuse

Public health authorities are continuing to receive reports relating to deaths and serious side effects in patients using fentanyl skin patches. This is despite the issue of numerous warnings and safety labelling changes issued in recent times. In late 2006, Slade Pharmacy and Galen Health released a medication safety alert outlining the dangers of fentanyl patches and recommendations for safe and appropriate use.

Health professionals who prescribe, dispense or administer fentanyl patches (Durogesic® Transdermal System) are strongly reminded that fentanyl skin patches are only indicated for *the management of persistent, moderate to severe chronic pain in opioid tolerant patients aged 12 years and older who require a total opioid dose at least equivalent to a 25 microgram / hour patch*. Re-iteration of the

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following safety concerns is important when considering analgesic skin patches:

- Do not use in opioid naïve patients with non cancer pain
- Extra care should be taken with use in the elderly due to a reduction in clearance and a prolonged half life of fentanyl
- Patches should not be cut or divided
- Increased body heat and direct heat at the application site may increase absorption
- Patches should not be replaced any earlier than 72 hours
- Safe disposal of patches by (folding the sticky side together until it sticks back on itself) is of utmost importance.

Health professionals are strongly urged to be mindful of the high risks associated with fentanyl patches and to use extreme caution and follow exact directions when prescribing, dispensing or administering.

Schedule 8 Drugs

Maintenance of a Schedule 8 drugs register in each and every pharmacy department is a legislative requirement in all states and territories in Australia. It is an essential part of the chain of control system to ensure safe and responsible transportation and storage of Schedule 8 medications from manufacturers and/or wholesalers to pharmacists and/or chief nurses and onto hospital wards and patients.

Authorities have noted a reduced compliance in maintaining registers and adherence to the process for responsible transportation of controlled drugs. It is imperative that all pharmacists, dispensary technicians, nursing staff and prescribers are familiar with the legislation surrounding supply, storage, recording and transportation of controlled drugs within healthcare institutions. Please be mindful of the following requirements when handling controlled drugs:

- All Schedule 8 drugs must be stored in a locked safe at all times
- A pharmacist, chief nurse or nurse in charge of a clinical area are the only persons authorised to be in possession of a key or access code to a schedule 8 drug safe
- Schedule 8 drugs must only be signed in and out of registers by authorised personnel – this is a pharmacist, doctor or a registered nurse (as governed by relevant state legislation)
- Registers must be completed at the point of each and every transaction
- Information recorded for each transaction must be complete and accurate and contain all the information listed in the Schedule 8 register as being required
- Balances must never be recorded as being negative
- All discrepancies must be reported without delay in line with hospital procedures and relevant state or territory legislation
- Transportation of all Schedule 8 drugs via couriers and dispensary assistants must ensure the chain of custody has not been broken between authorised personnel. Thus all items transported in this way must be in a securely sealed non transparent bag.
- All Schedule 8 drugs arriving from an external manufacturer or wholesaler must be delivered directly to a pharmacist or a chief nurse for receipt
- All transportation transactions must be recorded for and signed by both the person issuing the medication and the person receiving it to ensure the chain of custody between authorised personnel is not broken.

Further information about the legislation governing Schedule 8 medications can be sourced from the relevant drugs and poisons legislation in your state or territory.