

RGH Pharmacy E-Bulletin

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A joint initiative of the Patient Services Section and the Drug and Therapeutics Information Service of the Pharmacy Department, Repatriation General Hospital, Daw Park, South Australia. The RGH Pharmacy E-Bulletin is distributed in electronic format on a weekly basis, and aims to present concise, factual information on issues of current interest in therapeutics, drug safety and cost-effective use of medications.

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Thalidomide

The use of Thalidomide in the late 1950's was associated with congenital abnormalities causing severe birth defects in children born to women who had been prescribed this drug during pregnancy. This tragedy triggered a worldwide response and safety monitoring systems were set up in an attempt to prevent this tragedy from happening again.

Thalidomide is available today under very strict regulations and certain procedures must be followed in order to obtain it. It is approved for use for the following conditions:

- the treatment of multiple myeloma after failure of standard therapies
- the acute treatment of moderate to severe erythema nodosum leprosum (ENL)

Only specialists in oncology/haematology or in the management of leprosy should initiate treatment of patients with thalidomide.

The mechanism of action of thalidomide is not completely understood: it reduces levels of tumor necrosis factor alpha, but increases levels of interleukin 2 and interferon-gamma. It is an inhibitor of angiogenesis and inhibits basic fibroblast growth factor (bFGF) - bFGF has been shown to stimulate limb growth and its inhibition may be the basis for limb defects associated with thalidomide.

Adverse effects of thalidomide include drowsiness, somnolence, peripheral neuropathy (which can be irreversible), dizziness, orthostatic hypotension, neutropenia, skin rash, impaired wound healing, hypothyroidism and thromboembolic events. Caution is required especially in patients who are also receiving other treatments that potentiate the risk of thrombosis and the use of low-dose anticoagulation is recommended.

The Pharmion Risk Management Programme (PRMP) is designed to ensure that exposure of an unborn child to thalidomide does not occur. The pharmacy, prescriber and patient must be registered with PRMP before approval to supply thalidomide is provided. Patient and physician must complete a telephone survey and an authorization number will be issued to the physician for initial and ongoing treatment. Contraceptive counselling and pregnancy testing must be performed prior to initial prescribing and for further ongoing supply. Female patients of childbearing age must understand the need to avoid pregnancy and be counselled on the risk of birth defects, other side-effects and precautions. Two methods of birth control must be used at the same time at least four weeks before commencing treatment, for the duration of therapy, and for four weeks after ceasing thalidomide. Similarly, male patients must use additional contraception even if they have had a vasectomy. A maximum of four weeks supply is issued at any one time with authorization required for further supplies.

Further information is available from www.prmp.com and the password is available from Pharmion for registered pharmacies and prescribers.

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FOR FURTHER INFORMATION – CONTACT THE PHARMACY DEPARTMENT ON 82751763 or email: chris.alderman@rgh.sa.gov.au
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