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Your questions to the PBAC

Methotrexate

We would like to suggest a simple measure to reduce the risk of potentially life-threatening adverse effects associated with unintentional overdose of methotrexate. This problem has been highlighted in the past, with recommendations for clear labelling and patient counselling to minimise the risk.¹ Labels should name the specific weekday for dosing. The instruction to 'take as directed' is unacceptable.

Despite these measures, we continue to see patients suffering severe adverse effects because they have taken methotrexate daily instead of weekly as prescribed. These patients are often elderly and particularly susceptible to poor outcomes.

Maximum quantities of methotrexate allowed on the Pharmaceutical Benefits Scheme (PBS) are 30 and 15, for 2.5 mg and 10 mg tablets respectively. For a patient on a weekly dose of 15 mg, up to 15 weeks treatment can be dispensed at one time. Consequently, inappropriate daily use can continue for two weeks before a repeat is requested and there is an opportunity to spot the error.

If prescribers restrict the quantity of methotrexate ordered to a maximum of four weeks supply, as with most other PBS items, unintentional overdose could effectively be limited to just four days before repeat supply would have to be obtained. If pharmacists are alert for early requests for repeat supplies, this simple measure would greatly increase the chances of the patient error being noticed by a health professional, and potentially reduce the adverse consequences of such an error.

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REFERENCE

 Kanagarajah S. Perils and pitfalls of methotrexate prescription. Aust Prescr 2000;23:44-5.

The Pharmaceutical Benefits Advisory Committee responds:

Although a maximum quantity is set out in the Schedule of Pharmaceutical Benefits, there is flexibility to vary the quantity prescribed for those patients taking doses that are higher or lower than usual. It is the responsibility of the doctor to ensure that individual patients are prescribed the quantity which is most suitable for their needs.

If a prescriber believes a lesser quantity is sufficient for the patient's needs, then a quantity less than the listed maximum quantity may be prescribed and dispensed. Under the PBS, an allowance is paid to pharmacists for dispensing a lesser quantity from a standard pack.

At its March 2008 meeting, the Pharmaceutical Benefits Advisory Committee (PBAC) recommended the unrestricted listing of methotrexate 10 mg, in a smaller 15 tablet pack size. As a consequence, the PBAC also recommended a restricted benefit listing for the methotrexate 10 mg, 50 tablet pack size, limiting use to patients requiring a dose of more than 20 mg per week. The unrestricted benefit listing for methotrexate 2.5 mg remained unchanged.