



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

MEDIA STATEMENT

6th April 2009

CONSUMER MEDICINE RECALL

DITHRASAL 1% (dithranol 10mg/g) ointment 50g tube AUST R 15561
Batch number: 6A49 Expiry Date: July 2009

and

DITHRASAL 2% (dithranol 20mg/g) ointment 50g tube AUST R 15562
Batch number: 34526 Expiry Date: March 2011

Following consultation with Australia's medicines regulator, the Therapeutic Goods Administration (TGA) Dermatech Laboratories Pty Ltd, is recalling affected batches of Dithrasal Ointment (dithranol) due to contamination in the product.

The ointment, used for treatment of sub acute and chronic psoriasis of the scalp and body is sold through pharmacies in 50 gram tubes.

These batches of the product are being recalled because they contain higher than permitted levels of 1, 8 dihydroxyanthraquinone (DHAQ).

DHAQ is a known breakdown product of dithranol (the active ingredient in Dithrasal) and is permitted in the product at low levels.

High levels of DHAQ have been associated with the development of tumours in animal studies. Epidemiological studies have not demonstrated an association between DHAQ and the development of tumours in humans, however the product is being recalled as a precaution to avoid any potential safety risk to consumers.

If people have purchased the affected product, they should stop using it and contact their GP or dermatologist for ongoing treatment options.

Consumers who have concerns over their use of the product, should consult their medical practitioner.

Press advertising of the recall is expected to appear in state daily newspapers commencing Monday 6 April 2009.

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