



**- Please immediately bring to the attention of all doctors -**

Date: 06 April 2009

Contact telephone number: **8226 2578**

## **Recall of Dithrasal 1% & 2% (dithranol) ointment**

This notification is to alert medical practitioners about the recall of two batches of Dithrasal (dithranol) ointment. Dithrasal ointment is used for short contact treatment of subacute and chronic psoriasis of the body and scalp. Dithrasal ointment is sold through pharmacies.

The Therapeutic Goods Administration has issued a consumer level medicine recall for the following batches of Dithrasal ointment:

Dithrasal 1% (dithranol 10mg/g) ointment 50g tube  
AUST R 15561  
Batch No. 6A49; Expiry date July 2009;  
and  
Dithrasal 2% (dithranol 20mg/g) ointment 50g tube  
AUST R 15562  
Batch No. 34526; Expiry date March 2011.

These batches have been recalled because the product contains higher than permitted levels of an impurity 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.

While epidemiological studies have not demonstrated an association between DHAQ and the development of tumours in humans, the product is being recalled as a precaution to avoid any potential safety risk to consumers.

### **Advice to doctors**

Patients may seek advice about alternative products that may be used for the treatment of psoriasis. If use of a dithranol-containing product is the preferred treatment option and alternative batches of Dithrasal ointment are not available in pharmacies, some pharmacies may be able to prepare an extemporaneous preparation of dithranol ointment for patients.

### **Advice to consumers**

Consumers who have purchased the product included in the recall are advised to stop using it and contact their doctor or dermatologist about ongoing treatment options.

Consumers who have concerns about their use of the product should consult their doctor.

### **Additional information**

Consumers should return the product to the place of purchase for a refund or they can call the Dermatech customer service line on 1800 818 220.

**Professor Paddy Phillips – Chief Medical Officer, SA Health**

*Information contained within this advice should be treated as confidential and is for the intended recipient only.*

**PUBLIC HEALTH ALERT**