Submission for Reclassification of a Medicine

Part A

1. International Non-proprietary Name (or British Approved Name or US Adopted Name) of the medicine

   Corn Caps Salicylic Acid 40% w/w

2. Proprietary name(s)

   CARNATION Footcare
   CORN CAPS
   MEDICATED CORN REMOVERS
   Salicylic Acid 40% w/w

3. Name of company/organisation/individual requesting reclassification

   The Podiatrists' Board
   P O Box 10-140
   Wellington

4. Dose form(s) and strength(s) for which a change is sought

   Salcylic Acid 40%

5. Pack size and other qualifications

   5 MEDICATED PLASTERS

6. Indications for which change is sought

   Removal of hard corns

7. Present classification of medicine

   Pharmacy-Only Medicine

8. Classification sought

   Restricted Medicine (Pharmacist Only)

9. Classification status in other countries (especially Australia, UK, USA, Canada)

In Australia:
The products listed in 1. And 13. are all 'unscheduled'. Unscheduled over-the-counter non-prescription medicines are allowed to be sold anywhere, ie supermarkets and shops and not restricted to sale in pharmacies only.
Source: OTC Medicines Section, Therapeutic Goods Administration, Department of Health and Ageing.

In the United States:
Corn and callous removers can be sold as an over-the-counter (OTC) drug product under the OTC monograph. As a plaster the concentration of salicylic acid can be 12%-40%; as a collodion-like vehicle the concentration of salicylic acid can be 12%-17.6%.
Source: Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration.

Information has been sought from the United Kingdom and Canada but not yet received.

10. Extent of usage in NZ and elsewhere (e.g. sales volumes) and dates of original consent to distribute

The extent of usage in NZ is not known to the Podiatrists' Board. Anecdotally, Podiatrists' often see patients complaining of adverse outcomes after they have used corn "cures" in attempts to remove corns.

11. Labelling or draft labelling for the proposed new presentation(s)

The labelling should be amended in line with the recommendations of the Minutes of the Medicines Classification Committee meeting May 2002

12. Proposed warning statements if applicable

NOT TO BE USED BY PEOPLE WITH DIABETES, CIRCULATORY DISORDERS OR IMMUNE DEFICIENCIES.

13 Other porducts containing the same active ingredient(s) and which would be affected by the proposed changes

Scholl Callus removal pads
Salicylic Acid 38.01 mg (equiv. 40% w/w) AUST R 13517

Scholl Corn removal pads
Salicylic Acid 6.36 mg (equiv. 40% w/w) AUST R 13518

Scholl Corn removal plasters FABRIC
Salicylic Acid 6.36 mg (equiv 40% w/w) AUST R 13515

Scholl Corn removal plasters WASHPROOF
Salicylic Acid 6.36 mg (equiv. 40% w/w) AUST R 46407

Scholl Corn Between Toes removal pads
Salicylic Acid 6.36 mg (equiv. 40% w/w) AUST R 93882

Part B

Reasons for requesting classification change.
This section should be supported where relevant by the following:

1. A statement of the benefits to both the consumer and to the public expected from the proposed change

Corn care products containing 40% salicylic acid w/w can be purchased over the counter in New Zealand. Products for sale state clearly NOT TO BE USED BY DIABETICS and also caution about use by children and people with circulatory disorders.

The minutes of the May 2002 Medicines Classification Committee Meeting made the recommendation: *That Medsafe should be asked to include in the Regulatory Guidelines, a requirement for warnings on the packs against Use on moles, on the face or in the genital area.*
This requirement does not appear to be being followed.

Salicylic acid, first described as a treatment for keratotic lesions in ancient Greece, is believed to lower the PH of the stratum corneum, thereby leading to swelling, maceration and eventual desquamation of the lesion (Menz 2008). Maceration also breaches the integrity of the skin, increasing the risk of bacterial and fungal infection. People with compromised immunity are vulnerable to opportunistic infections and many chemotherapeutic drugs may delay healing of wounds that result from the action of salicylic acid.

2. Ease of self-diagnosis or diagnosis by a pharmacist for the condition indicated

Corns and calluses are mostly self-diagnosable, although corns and verrucae are often confused. However the causes of keratotic lesions are often misunderstood. In response to repetitive friction or pressure normal healthy skin undergoes accelerated keratinisation and a decreased rate of desquamation, resulting in an increase in the thickness of the stratum corneum (Rubin 1949).

A pharmacist may not diagnose a corn or a callous as a pressure lesion but could easily establish if the client was at risk of adverse effects from the use of products containing 40% salicylic acid.

3 Relevant comparative data for like compounds

4. Local data or special considerations relating to NZ

5. Interactions with other medicines

6. Contraindications

7. Possible resistance

8. Adverse events – nature, frequency etc.

Adverse events do occur. Generally podiatrists are able to resolve the ulcerations and minor infections that present after use of corn care products. Sometimes it is necessary to refer for antibiotic cover.

A brief case history is appended below.

9. Potential for abuse or misuse

REFERENCES

Menz, H B (2008) Foot Problems in Older People. Assessment and Management. Sydney, Churchill Livingstone Elsevier p.70

Rubin, L. Hyperkeratosis in response to mechanical irritation. Journal of Investigative Dermatology 1949; 13: 313-315

Case history

35 year old female being treated for scleroderma and rheumatoid arthritis used a CARNATION CORN CAP as a “first aid “ measure before the podiatrist’s visit in two days. After 48 hours there was a full thickness dissolution of the epidermis at the corn site.

Other medications; Intagram P (Immunoglobulin)
Cyclosporin
Prednisone
Methotrexate

There was also a history of recent hospitalisation for cellulitis after a minor hand injury.

If a pharmacist had been consulted before this product had been used they would have realised that it was not a safe treatment for this client.

N.B. This adverse reaction was reported to CARM.