1. Assessment of efficacy
   a. Have all relevant studies on efficacy been included
      Yes ✓
      Trial data are scarce, a Cochrane review summarizing these has been submitted.
   
b. Summarize the data on efficacy, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)

   As an old medication there is very little supportive clinical trial data of sufficient strength. A Cochrane review of the treatment of plaque type psoriasis with topical medications found that it was more effective than placebo. No trial of scalp, nail or inverse psoriasis was identified. The treatment duration ranged from three to eight weeks. Total Severity Score (TSS) Psoriasis Area Severity Index (PASI), Investigator Assessment of Global Improvement (IAGI), Patient Assessment of Global Improvement (PAGI) were the scoring systems used. Comparisons with Vitamin D products, gave mixed results in this review largely because of the heterogeneity of the studies with varying durations of treatment from 4 to 12 weeks. Also three different formulations of Vitamin D analogues were used e.g. calcitriol, calcipotriol and tacalcitol. No significant differences in efficacy versus dithranol were found.

   c. Please provide any additional relevant information with reference

      NA

2. Assessment of safety
   a. Have all relevant studies on safety been included
      Yes ✓
   
b. Summarize the data on safety, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)

   Itching and burning are common. In a systematic review of adverse events with topical treatments in psoriasis, dithranol performed worst with 72% patients having adverse events. In addition, severe staining of the skin and clothing is seen in almost all cases. Irritation is almost universal although a scheme for reducing the exposure time and hence the risk or adverse effects, through short term use, has been developed and advocated. The usual recommendation for an application time on these sites has been 30 minutes in order to avoid the side effect of burning. It seems to be without long term local, systemic or teratogenic effects.

   c. Please provide any additional relevant information with reference

      NA
3. Assessment of cost and availability
   a. Have all relevant data on cost provided
      NA (an application for deletion)
   b. Summarize the data on cost and cost effectiveness, in comparison to what is listed in EML where applicable (limit to 2 to 3 sentences)
      NA (an application for deletion)
   c. Please provide any additional relevant information with reference
      NA
   d. Is the product available in several low and middle income countries?
      Yes

4. Assessment of public health need
   a. Please provide the public health need for this product (1-2 sentences)

   Psoriasis is a common chronic skin disorder. The prevalence of psoriasis is relatively high in the general population, ranging between 0.6% and 4.8%, mainly as a result of chronicity and the absence of a cure. Numerous topical and systemic therapies are available for the treatment of psoriasis. Treatment modalities are chosen on the basis of disease severity, relevant comorbidities, patient preference (including cost and convenience), efficacy, and evaluation of individual patient response. With the current treatment options the primary goal of treatment is control of the disease rather than cure.

   b. Do guidelines (especially WHO guidelines) recommend this product? If yes, which ones? List 1 or 2 international preferable
      Yes (e.g. UK, Canada, NZ, USA)

5. Are there special requirements for use or training needed for safe/effective use?
   Trained health care professionals and training for patients are necessary for the safe use.

6. Is the proposed product registered by a stringent regulatory authority?
   Yes ✓

7. Any other comments
   NA

8. What is your recommendation to the committee (please provide the rationale)

   The product is of established efficacy, although the trial data of today’s standard are scarce. Trained health care professionals and careful patient instruction are necessary for its safe use. The cost is on the low side, but the availability may not be universal.

Dithranol deletion
Nevertheless, while the biological medicinal products have widened the treatment options in the high income countries, the treatment of psoriasis remains a challenge, especially where the new treatments are out of financial reach.

The conditions needed for the safe use of the product may be achievable in many settings. Of note, it has been retained also in the guidelines of the high income regions.

The Committee is recommended to maintain the current listing of dithranol.