

## Indications for Use

510(k) Number (if known)

K143590

Device Name

Eczemol OTC

Indications for Use (Describe)

OTC Indication: Eczemol OTC is indicated to manage and relieve the burning, itching and pain experienced with various types of dermatoses, including radiation dermatitis and atopic dermatitis. Eczemol OTC may be also used to relieve to pain of first-and second-degree burns. Helps to relieve dry waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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