Drithocreme®
(anthralin) 1.0% (HP)

Description
Drithocreme® is a pale yellow topical cream containing 1.0% (HP) anthralin USP in a base of white petrolatum, sodium lauryl sulfate, cetostearyl alcohol, ascorbic acid, salicylic acid, methylparaben and purified water. The chemical name of anthralin is 1,8-dihydroxy-9-anthrone. The structural formula is:

![Structural formula of anthralin](image)

Clinical Pharmacology
Although the precise mechanism of anthralin's anti-psoriatic action is not fully understood, in vitro evidence suggests that its antimitotic effect results from inhibition of DNA synthesis. Additionally, the chemically reducing properties of anthralin may upset oxidative metabolic processes, providing a further slowing down of epidermal mitosis.

Absorption in man has not been finally determined, but in a limited clinical study of Drithocreme, no traces of anthraquinone metabolites were detected in the urine of subjects treated; however, caution is advised in patients with renal disease.

Indications and Usage
An aid in the topical treatment of quiescent or chronic psoriasis. Treatment should be continued until the skin is entirely clear, i.e., when there is nothing to feel with the fingers and the texture is normal.

Contraindications
Do not use Drithocreme on the face, or for acute or actively inflamed psoriatic eruptions. Do not use if sensitive to any of the ingredients.

Warnings
Avoid contact with the eyes or mucous membranes. Drithocreme should not normally be applied to intertriginous skin areas. Remove any unintended residue which may be deposited behind the ears. Avoid applying to the folds and creases of the skin. Discontinue use if a sensitivity reaction occurs or if excessive irritation develops on uninvolved skin areas. Keep out of the reach of children.

Precautions
For external use only. To prevent the possibility of staining clothing or bed linen while gaining experience in using Drithocreme, it may be advisable to use protective dressings. To prevent the possibility of discoloration, always rinse the bath/shower with hot water immediately after washing/showering and then use a suitable cleanser to remove any deposit on the surface of the bath or shower. Contact with fabrics, plastics and other materials may cause staining and should be avoided. Always wash hands thoroughly after use. Long-term studies in animals have not been performed to evaluate the carcinogenic potential of the drug. Although anthralin has been found to have tumor-promoting properties on mouse skin, there have been no reports to suggest carcinogenic effects in humans after many years of clinical use. As long-term use of topical corticosteroids may destabilize psoriasis, and withdrawal may also give rise to a 'rebound' phenomenon, an interval of at least one week should be allowed between the discontinuance of such steroids and the commencement of Drithocreme therapy. Petrolatum or a suitably bland emollient may usefully be applied during the intervening period.

Pregnancy
Pregnancy Category C. Animal reproduction studies have not been conducted with Drithocreme. It is also not known whether Drithocreme can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Drithocreme should be given to a pregnant woman only if clearly needed.
Nursing Mothers
It is not known whether this drug is excreted in human milk. Because many drugs are excreted in milk and because of the potential for tumorigenicity shown for anthralin in animal studies, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use
Safety and effectiveness in pediatric patients have not been established.

Adverse Reactions
Very few instances of contact allergic reactions to anthralin have been reported. However, transient primary irritation of uninvolved skin surrounding the treated lesions is more frequently seen and may occasionally be severe. Application of Drithocreme must be restricted to the psoriatic lesions. If the initial treatment produces excessive soreness or if the lesions spread, reduce frequency of application and, in extreme cases, discontinue use and consult physician. Some temporary discoloration of hair and fingernails may arise during the period of treatment but should be minimized by careful application. Drithocreme may stain skin, hair or fabrics. Staining of fabrics may be permanent, so contact should be avoided.

Dosage and Administration
Generally, it is recommended that Drithocreme be applied once a day or as directed by a physician. Anthralin is known to be a potential skin irritant. The irritant potential of anthralin is directly related to each patient's individual tolerance. Therefore, where the response to anthralin treatment has not previously been established, always commence treatment using a short contact time of 5 to 10 minutes for at least one week using Drithocreme. Contact time can be increased stepwise to twenty to thirty minutes, or as directed by a physician, before removing the cream by thoroughly washing or showering. To open the tube, unscrew the cap and invert to pierce the membrane. Apply as directed by a physician. The optimal period of contact will vary according to the patient's response to treatment.

For the Skin
Apply sparingly only to the psoriatic lesions and rub gently and carefully into the skin until absorbed. It is most important to avoid applying an excessive quantity which may cause unnecessary soiling and staining of the clothing and/or bed linen. At the end of each period of treatment, a bath or shower should be taken to remove any surplus cream (which may have become red/brown in color). The margins of the lesions may gradually become stained purple/brown as treatment progresses, but this will disappear after cessation of treatment.

For the Scalp
Comb the hair to remove scalar debris and, after suitably parting, rub the cream well into the lesions. Keep Drithocreme away from the eyes. Care should be taken to avoid application of the cream to uninvolved scalp margins. Remove any unintended residue which may be deposited behind the ears. At the end of each period of contact, wash the hair and scalp to remove any surplus cream (which may have become red/brown in color). Keep tightly capped when not in use.

Store at controlled room temperature, 15˚-30˚C (59˚-86˚F).

How Supplied
50 g tube
Drithocreme 1.0%  NDC 11086-037-01

Rx Only
Distributed by
Summers Laboratories, Inc.
Collegeville, PA 19426

Manufactured for
Summers Laboratories by:
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Limited Canada
Mississauga, Ontario
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Rev. 10/2006