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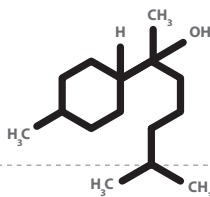
Trioxil ANTI-ACNE GEL

Trioxil (bisazulene gel) 14%

FOR TOPICAL USE ONLY. NOT FOR OPHTHALMIC, ORAL, OR INTRAVAGINAL USE.

DESCRIPTION:

Trioxil (bisazulene gel) 14%, is a formulation containing 14%, by weight, bisazulene for topical treatment of acne vulgaris. This formulation uses tiny micro spheres called nanosomes that are used to encapsulate the active ingredient, bisazulene, in a gel compound. Other components of this formulation are purified water, arnica nanosomes, D-Panthenol nanosomes, witch hazel, ginseng extract, yeast and horse chestnut, alpha bisabolol, tea tree oil, isopropyl myristate, polysorbate 80, triethanolamine, carbomer, and methyl paraben. Chemically, bisazulene, also known as 1-Methyl-4(1,5-dimethyl-1-hydroxyhex-4(5)-enyl)-cyclohexen-1; 6-Methyl-2-(4-methyl-3-cyclohexen-1-yl)-5-hepten-2-ol is a metabolite of chamomile flowers. Bisazulene has the following structure:



Trioxil (bisazulene gel) 14% is the newest compound developed in the fight against acne and has several unique advantages over other acne medications. Trioxil (bisazulene gel) 14% achieves a remarkable reduction in acne lesions with no incidence of side effects and without the typical drying, redness, and swelling caused by other popular formulations containing benzoyl peroxide, salicylic acid, or tretinoin. Most patients will notice an improvement in skin texture and smoothness including a reduction in acne lesions.

CLINICAL PHARMACOLOGY:

Bisazulene is a chemically stable, alpha bisabolol-like compound. Pharmacological profile studies have demonstrated that bisazulene is a modulator of epithelial cell growth and differentiation, keratinization, inflammatory, and anti-bacterial processes all of which represent the pathology of acne vulgaris.

Although the exact mode of action of bisazulene is unknown, it is suggested that topical bisazulene may normalize the differentiation of follicular epithelial cells, reduce inflammation, and has strong antimicrobial activity resulting in decreased microcomedone formation.

Bisazulene has soothing and calming properties on human skin further improving the overall skin condition.

Pharmacokinetics: Clinical pharmacokinetic studies have not been performed with Trioxil (bisazulene gel) 12%. Absorption of bisazulene through human skin does not pose any health risks.

CONTRAINDICATIONS:

Although sensitivity reactions have never been observed, this formulation is contraindicated in individuals with a history of sensitivity reactions to any of its components. It should be discontinued if hypersensitivity to any of its ingredients is noted.

GENERAL:

-A very small number of individuals may experience dryness, redness, or peeling at the beginning of treatment. This is only temporary and should resolve within a few days. If the degree of irritation warrants, patients should be directed to temporarily reduce the amount or frequency of application of the medication.

- It is not necessary to avoid exposure to sunlight since Trioxil does not increase or alter sensitivity to the sun. However patients with sunburn should be advised not to use the product until fully recovered because the effect of bisazulene on sunburned skin is unknown.

- Trioxil (bisazulene gel) 14%, should be kept away from the eyes, the mouth, paranasal creases of the nose, and mucous membranes.

- The use of a moisturizer during treatment is not necessary because Trioxil (bisazulene gel) 14% has

a deeply soothing and calming effect on the skin.

- To maximize the results of the treatment, Hydroviton CR liquid normalizing soap should be used as a cleanser before applying Trioxil (bisazulene gel) 14%.

Drug Interactions: Concomitant use of other potentially irritating topical products (medicated or abrasive soaps and cleansers, soaps and cosmetics that have a strong drying effect, and products with high concentrations of alcohol, astringents, spices, or lime) should be avoided during treatment with Trioxil (bisazulene gel) 14% or approached with caution. Particular caution should be exercised in using preparations containing sulfur, resorcinol, or salicylic acid in combination with Trioxil (bisazulene gel) 14%.

Nursing Mothers: It is not known whether bisazulene is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Trioxil (bisazulene gel) 14% is administered to a nursing woman.

DOSAGE AND ADMINISTRATION:

Trioxil (bisazulene gel) 14% should be applied once a day to affected areas after washing in the evening before retiring. A thin film of the gel should be applied, avoiding eyes, lips, and mucous membranes. During the early stages of therapy, in a small number of patients acne may actually appear to become worse. This is due to the action of the medication on previously unseen lesions and therapy should not be discontinued. Full therapeutic benefit should be noticed after eight to twelve weeks of treatment.

OVERDOSAGE:

If the medication is applied excessively, no more rapid or better results will be obtained.

For Patients

QUESTIONS AND ANSWERS:

Q: Does Trioxil (bisazulene gel) 14% dry the skin?

A: No, because drying the skin causes the body to produce even more oil, creating a vicious circle. The treatment removes excess oil while deeply moisturizing the skin at the same time.

Q: How long does it take before the first results can be seen?

A: During the first week it is possible to see the control of oiliness and the reduction in skin eruptions. Within a few weeks the treatment begins to normalize sebaceous secretion, reducing inflammation and making the skin smoother and healthier.

Q: Do I need to use a Toning Lotion before using Trioxil (bisazulene gel) 14%?

A: No, the Gel has its own toning and astringent effect.

Q: If I stop the treatment will the acne return?

A: There is no cure for acne, so it is necessary to continue the treatment for as long as the problem persists.

Q: Why is it more common to have problems with acne during adolescence and what causes acne in adults?

A: During adolescence there is an increase in the production of testosterone (the male hormone present in both sexes), which makes the sebaceous glands more active. During adulthood it is common to experience the same hormonal imbalance due to stress or menopause. The use of some types of medicine, inappropriate cosmetics, excess exposure to sunlight and eating certain foods can also cause acne in both adolescents and adults.

Q: Can Trioxil (bisazulene gel) 14% treatment cause allergies?

A: Trioxil (bisazulene gel) 14% is hypoallergenic and therefore does not cause allergies in the vast majority of people. In exceptional cases of hypersensitivity to one of the ingredients, treatment must be stopped immediately and medical advice sought.

Q: The second time I bought Trioxil (bisazulene gel) 14% I noticed that it was a different color. Is this normal?

A: Yes. The vegetable extracts contained in the gel can change color depending on the harvest or the way the plants are gathered. Changes in color may be more noticeable in our products due to the high concentration of these extracts and the fact that we do not use artificial colorants.

Manufactured by:

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