

**DESCRIPTION:**

Zaclir 4% and Zaclir 8% Cleansing Lotions are a topical preparation containing benzoyl peroxide as the active ingredient. Zaclir 4% and Zaclir 8% Cleansing Lotions contain benzoyl peroxide 4% and 8%, respectively, in a lathering vehicle.

**CLINICAL PHARMACOLOGY:**

The exact method of action of benzoyl peroxide in acne vulgaris is not known. Benzoyl peroxide is an antibacterial agent with demonstrated activity against *Propionibacterium acnes*. This action, combined with the mild keratolytic effect of benzoyl peroxide is believed to be responsible for its usefulness in acne. Benzoyl peroxide is absorbed by the skin where it is metabolized to benzoic acid and excreted as benzoate in the urine.

**INDICATIONS AND USAGE:**

Zaclir 4% and Zaclir 8% Cleansing Lotions are indicated for use in the topical treatment of mild to moderate acne vulgaris. Zaclir 4% and Zaclir 8% Cleansing Lotions may be used as an adjunct in acne treatment regimens including antibiotics, retinoic acid products, and sulfur/salicylic acid containing preparations.

**CONTRAINDICATIONS:**

Zaclir 4% and Zaclir 8% Cleansing Lotion should not be used in patients who have shown hypersensitivity to benzoyl peroxide or to any of the other ingredients in the product.

**PRECAUTIONS:**

General - For external use only. Avoid contact with eyes and mucous membranes. AVOID CONTACT WITH HAIR, FABRICS OR CARPETING AS BENZOYL PEROXIDE WILL CAUSE BLEACHING.

Carcinogenesis, Mutagenesis, Impairment of Fertility - Based upon all available evidence, benzoyl peroxide is not considered to be a carcinogen. However, data from a study using mice known to be highly susceptible to cancer suggest that benzoyl peroxide acts as a tumor promoter. The clinical significance of the findings is not known.

Pregnancy: Category C- Animal reproduction studies have not been conducted with benzoyl peroxide. It is also not known whether benzoyl peroxide can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Benzoyl peroxide should be used by 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 human milk, caution should be exercised when benzoyl peroxide is administered to a nursing woman.

Pediatric Use - Safety and effectiveness in children below the age of 12 have not been established.

**ADVERSE REACTIONS:**

Contact sensitization reactions are associated with the use of topical benzoyl peroxide products and may be expected to occur in 10 to 25 of 1000 patients. The most frequent adverse reactions associated with benzoyl peroxide use are excessive erythema and peeling which may be expected to occur in 5 of 100 patients. Excessive erythema and peeling most frequently appear during the initial phase of drug use and may normally be controlled by reducing frequency of use.

**DOSAGE AND ADMINISTRATION:**

Shake well before using. Wash the affected areas once a day during the first week, and twice a day thereafter as tolerated. Wet skin areas to be treated; apply Zaclir 4% or Zaclir 8% Cleansing Lotions, work to a full lather, rinse thoroughly and pat dry. Frequency of use should be adjusted to obtain the desired clinical response. Clinically visible improvement will normally occur by the third week of therapy. Maximum lesion reduction may be expected after approximately eight to twelve weeks of drug use. Continuing use of the drug is normally required to maintain a satisfactory clinical response.

**HOW SUPPLIED:**

Zaclir 4% Cleansing Lotion is supplied in 10.5 oz (297 g) plastic bottles, NDC 63717-030-11, and 2 mL sample pouch pack, NDC 63717-030-99.

Zaclir 8% Cleansing Lotion is supplied in 10.5 oz (297 g) plastic bottles, NDC 63717-031-11, and 2 mL sample pouch pack, NDC 63717-031-99.

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

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Manufactured by: Sheffield Laboratories, New London, CT 06320

Manufactured for: Hawthorn Pharmaceuticals, Inc., Madison, MS 39110

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