MICROGEL™ FORMULA

5 Benzagel® & 10 Benzagel®
Acne Gel
(benzoyl peroxide gel)

DESCRIPTION: Each gram of 5 Benzagel® and 10 Benzagel® contains 50 mg and 100 mg respectively, of benzoyl peroxide in a gel vehicle of purified water, carbomer 940, 14% alcohol, sodium hydroxide, docusate sodium and fragrances.

Benzoyl peroxide is an antibacterial and keratolytic agent. The structural formula is:

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\text{Hydrous Benzoyl Peroxide}
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CLINICAL PHARMACOLOGY: Benzoyl peroxide is an antibacterial agent which has been shown to be effective against Propionibacterium acnes. This action is believed to be responsible for its usefulness in acne. One study in the rhesus monkey demonstrated a percutaneous absorption of about 1.8 μg per cm² of benzoyl peroxide or 45% of the applied dose in a 24-hour period. The absorbed benzoyl peroxide was completely converted in the skin to benzoic acid.

INDICATIONS AND USAGE: 5 & 10 Benzagel may be used alone topically for mild to moderate acne and as an adjunct in acne treatment regimens which might include retinoic acid products, systemic antibiotics, and/or sulfur and salicylic acid containing preparations. The active ingredient, benzoyl peroxide, exerts a desquamative and antibacterial action. It provides mild peeling and keratolytic activity.

CONTRAINDICATIONS: Benzagel should not be used by patients having known sensitivity to benzoyl peroxide or any of its components.

WARNINGS: If itching, redness, burning, swelling or undue dryness occurs, discontinue use.

PRECAUTIONS: For external use only. Not for ophthalmic use. Keep away from eyes and mucosae. Very fair individuals should begin with a single application at bedtime allowing overnight medication. May bleach colored fabrics. Keep this and all medications out of the reach of children.

Carcinogenesis, Mutagenesis and Impairment of Fertility: Long-term studies in animals have not been performed to evaluate carcinogenic potential.

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 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 human milk, caution should be exercised when benzoyl peroxide is administered to a nursing woman.

**Pediatric Use:** Safety and effectiveness in pediatric patients under the age of 12 have not been established.

**ADVERSE REACTIONS:** Irritation and contact dermatitis are the most frequent side reactions to benzoyl peroxide.

**DOSAGE AND ADMINISTRATION:** Wash and dry affected areas prior to application. Apply sparingly one or more times daily.

**HOW SUPPLIED:** 5 Benzagel is available in 1.5 oz. (42.5g) (NDC 0066-0430-15) plastic tubes; 10 Benzagel is available in 1.5 oz. (42.5 g) (NDC 0066-0431-15) plastic tubes.

5 Benzagel contains 50 mg of benzoyl peroxide per gram and 10 Benzagel contains 100 mg of benzoyl peroxide per gram.

Store at Controlled Room Temperature 20 to 25°C (68 to 77°F) [See USP].

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Rx Only

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