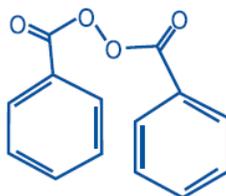


MICROGEL™ FORMULA

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:
Hydrous Benzoyl Peroxide



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

Mfd for: Dermik Laboratories
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