

NeoBenz[®] Micro

(benzoyl peroxide cream 5.5%)

NeoBenz[®] Micro SD

(benzoyl peroxide cream 5.5%) Pre-filled Sponge Applicator

NeoBenz[®] Micro Wash

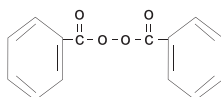
(benzoyl peroxide 7%)

Rx ONLY.

FOR EXTERNAL USE ONLY.

I. DESCRIPTION: NeoBenz[®] Micro 5.5% cream, NeoBenz[®] Micro SD 5.5% single dose cream pre-filled sponge applicator and NeoBenz[®] Micro Wash 7% are topical preparations containing benzoyl peroxide as the active ingredient incorporated into patented porous microspheres (MICROSPONGE[®] delivery system) composed of methyl methacrylate/glycol dimethacrylate crosspolymer. This polymeric system has been shown to provide gradual release of active ingredient into the skin¹ and absorb natural skin oils². Ingredients for the cream and SD include: C13-14 isoparaffin, cetyl alcohol, citric acid, ethylhexyl palmitate, glycerin, glyceryl dilaurate, laureth-7, magnesium aluminum silicate, methyl methacrylate/glycol dimethacrylate crosspolymer, methylparaben, polyacrylamide, propylparaben, silica, sodium citrate, sodium lauryl sulfate, sorbitol, stearyl alcohol, water, xanthan gum. Ingredients for the Wash include citric acid, cocamidopropyl betaine, cocamine oxide, disodium laureth sulfosuccinate, edetate disodium, fragrance, glycerin, hydrogenated castor oil, hypromellose, magnesium aluminum silicate, methyl methacrylate/glycol dimethacrylate crosspolymer, methylparaben, PEG-150 pentaerythrityl tetrastearate (and) PEG-6 caprylic/capric glycerides, PEG-40 hydrogenated castor oil, poloxamer 182, purified water, and xanthan gum.

Benzoyl peroxide is an oxidizing agent that possesses antibacterial properties and is classified as a keratolytic. Benzoyl peroxide (C₁₄H₁₀O₄) is represented by the following structure:



II. 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.

III. INDICATIONS AND USAGE: NeoBenz[®] Micro, NeoBenz[®] Micro SD and NeoBenz[®] Micro Wash are indicated for use in the topical treatment of mild to moderate acne vulgaris.

IV. CONTRAINDICATIONS: NeoBenz[®] Micro, NeoBenz[®] Micro SD and NeoBenz[®] Micro Wash should not be used in patients who have shown hypersensitivity to benzoyl peroxide or to any of the other ingredients in the products.

V. WARNINGS: When using this product, avoid unnecessary sun exposure and use a sunscreen.

VI. PRECAUTIONS (SEE WARNINGS):

General - For external use only. Avoid contact with eyes and mucous membranes. If severe irritation develops, discontinue use and institute appropriate therapy.

Information for Patients: Avoid contact with eyes, eyelids, lips and mucous membranes. If accidental contact occurs, rinse with water. AVOID CONTACT WITH HAIR, FABRICS OR CARPETING AS BENZOYL PEROXIDE WILL CAUSE BLEACHING OR DISCOLORATION. If excessive irritation develops, discontinue use and consult your physician.

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 this finding 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.

VII. ADVERSE REACTIONS: Allergic contact dermatitis and dryness have been reported with topical benzoyl peroxide therapy.

VIII. OVERDOSAGE: If excessive scaling, erythema or edema occurs, the use of these preparations should be discontinued. To hasten resolution of the adverse effects, cool compresses may be used. After symptoms and signs subside, a reduced dosage schedule may be cautiously tried if the reaction is judged to be due to excessive use and not allergenicity.

IX. DOSAGE AND ADMINISTRATION: NeoBenz[®] Micro, NeoBenz[®] Micro SD and NeoBenz[®] Micro Wash should be used once or twice daily on the affected areas. Frequency of use should be adjusted to obtain the desired clinical response. If you see medication or white residue on skin after application of NeoBenz[®] Micro or NeoBenz[®] Micro SD, you are applying too much. Gentle cleansing of the affected areas with a mild cleanser prior to application of NeoBenz[®] Micro or NeoBenz[®] Micro SD may be beneficial. 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.

NeoBenz® Micro: If applying to the entire face, apply a pea-sized amount of NeoBenz® Micro to one fingertip and dab onto cheeks, forehead and chin. Spread evenly onto entire face.

NeoBenz® Micro SD: Firmly squeeze cream pre-filled sponge applicator until seal between applicator and sponge has broken. Apply medication by rubbing sponge in small circular motions on affected areas.

Dispose of each applicator after single use only.

NeoBenz® Micro Wash: Shake well before using. Wet skin areas to be treated; apply NeoBenz® Micro Wash by massaging gently into skin for 10-20 seconds, working into a full lather. Rinse thoroughly and pat dry.

X. HOW SUPPLIED:

NeoBenz® Micro SD is supplied as follows:

SIZE: 1 box of thirty 0.5 gram applicators

NDC NUMBER: 10922-821-30

(benzoyl peroxide cream 5.5%) Pre-filled Sponge Applicator

NeoBenz® Micro Wash Plus Pack

NDC NUMBER: 10922-822-23

Contains:

1 tottle (180 gram), NeoBenz® Micro Wash (benzoyl peroxide 7%)

1 convenient travel case containing seven 0.5 gram applicators, NeoBenz® Micro SD (benzoyl peroxide cream 5.5%) Pre-filled Sponge Applicator

NeoBenz® Micro Cream Plus Pack

NDC NUMBER: 10922-823-23

Contains:

1 tube (45 gram), NeoBenz® Micro (benzoyl peroxide cream 5.5%)

1 convenient travel case containing seven 0.5 gram applicators, NeoBenz® Micro SD (benzoyl peroxide cream 5.5%) Pre-filled Sponge Applicator

Store between 15°-25°C (59°-77°F)

REFERENCES:

1. Wester RC, Patel R, Nacht S, Leyden J, Melendres J, Maibach H. Controlled release of benzoyl peroxide from a porous microsphere polymeric system can reduce topical irritancy. *J. Am. Acad. Dermatol.* 1991; 24: 720-726.

2. Meyer R. Rosen (ed.), *Delivery System Handbook for Personal Care and Cosmetic Products*, 332-352 (2005).

Covered by US Patents: 4,690,825; 5,145,675; 5,879,716; 6,007,364.

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