

NEOBENZ(R) MICRO BENZOYL PEROXIDE WASH, 7% - benzoyl peroxide, 7% lotion
SkinMedica Pharmaceuticals, Inc., Carlsbad, CA 92010

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

NeoBenz® Micro
(benzoyl peroxide cream)

NeoBenz® Micro SD
(benzoyl peroxide cream)

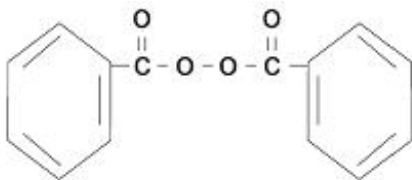
NeoBenz® Micro Wash
(benzoyl peroxide)

Rx ONLY.
FOR EXTERNAL USE ONLY.

I. DESCRIPTION

NeoBenz® *Micro* 3.5% and 5.5% creams, NeoBenz® *Micro* SD 5.5% single dose cream 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 all cream and SD strengths include: water, glycerin, ethylhexyl palmitate, sorbitol, cetyl alcohol, glyceryl ditaurate, stearyl alcohol, magnesium aluminum silicate, methyl methacrylate/glycol dimethacrylate crosspolymer, silica, citric acid, xanthan gum, methylparaben, sodium citrate, propylparaben, polyacrylamide, C13-14 isoparaffin, laureth-7, sodium lauryl sulfate. 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 moderated 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 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.

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 if therapy. Maximum lesion reduction may be expected after approximately eight to twelve weeks for 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 applicator until seal between applicator and sponge has broken. Apply medication by rubbing sponge on 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* is supplied as follows:

SIZE: 45 gram tube

NDC NUMBER:

(3.5% benzoyl peroxide cream): 67402-020-45

(5.5% benzoyl peroxide cream): 67402-021-45

NeoBenz® *Micro* SD is supplied as follows:

SIZE: 1 box of thirty 0.5 gram applicators

NDC NUMBER:

(5.5% benzoyl peroxide cream): 67402-021-06

NeoBenz® *Micro* Wash is supplied as follows:

SIZE: 180 gram tottle

NDC NUMBER:

(benzoyl peroxide 7%): 67402-027-17

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).

Distributed by SkinMedica Pharmaceuticals, Inc., Carlsbad. CA 92010

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

*MICROSPONGE® is a registered trademark of AMCOL Health and Beauty Solutions, Inc, a subsidiary of AMCOL International Corporation.

NeoBenz Micro Wash, Benzoyl Peroxide 7%

DIRECTIONS: Shake well before using. Wet skin areas to be treated; apply NeoBenz[®] Micro Wash (benzoyl peroxide 7%) by massaging gently into skin for 10-20 seconds, working into a lather. Rinse thoroughly and pat dry. Avoid contact with eyes.

ACTIVE INGREDIENTS: Benzoyl Peroxide 7%

INACTIVE INGREDIENTS: Citric Acid, Cocamidopropyl Betaine, Cocamine Oxide, Disodium Lauryl Sulfosuccinate, Ethanol, Potassium Fragrance, Glyceryl Hydrogenated Castor Oil, Hydroxyethylcellulose, Magnesium Aluminum Silicate, Methyl Methacrylate/Glycol Dimethacrylate Copolymer, Methylparaben, PEG-150, Polyethylene Glycol, Polyethylene Glycol-6-Caprylate/Capric Glycolides, PEG-40 Hydrogenated Castor Oil, Poloxamer 182, Purified Water and Xanthan Gum.

WARNINGS: KEEP OUT OF REACH OF CHILDREN. For External Use Only. When using this product, avoid unnecessary sun exposure and use a sunscreen. Benzoyl peroxide may bleach clothes or dyed fabric. See package insert for full prescribing information.

Store between 15°-25° C (59°-77°F). Expiration date and lot number below. Covered by US Patent Nos. 4,300,885 and 5,146,875 and 5,873,713.

Distributed by: SkinMedica, Inc.
Carlsbad, CA 92008

101411B

NeoBenz[®] Micro Wash
(benzoyl peroxide 7%)

NDC 67402-027-17
Rx Only

Net Wt 6.35 oz (180g)
101411B



NEOBENZ(R) MICRO BENZOYL PEROXIDE WASH, 7%

benzoyl peroxide, 7% lotion

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:67402-027
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	70 mg in 1 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67402-027-17	180 g in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved other		12/15/2008	

Labeler - SkinMedica Pharmaceuticals, Inc., Carlsbad, CA 92010 (124977005)

Revised: 7/2009

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