

PANOXYL - benzoyl peroxide soap
Physicians Total Care, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredient (Maximum Strength)

Benzoyl peroxide 10%

Active ingredient (Regular Strength)

Benzoyl peroxide 5%

Purpose

Acne medication

Use for the treatment of acne; helps prevent new acne blemishes from forming

Warnings

For external use only

Do not use

- if you have very sensitive skin
- if you are sensitive to benzoyl peroxide

When using this product

- skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time
- avoid unnecessary sun exposure and use a sunscreen
- avoid contact with the eyes, lips, and mouth
- avoid contact with hair and dyed fabrics, which may be bleached by this product
- skin irritation may occur, characterized by redness, burning, itching, peeling, or possibly swelling. Irritation may be reduced by using the product less frequently or in a lower concentration.

Stop use and ask a doctor if

- irritation becomes severe.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- using warm water, wash the affected area for 1 to 2 minutes
- rinse well and pat dry with a clean towel
- because too much drying of the skin may occur, start with 1 application daily, then gradually

increase to 2 or 3 times daily if needed or as directed by a doctor

- if bothersome dryness or peeling occurs, reduce application to once a day or every other day
- If going outside, apply sunscreen after using this product. If irritation or sensitivity develops, stop use of both products and ask a doctor.

Other information

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

Inactive ingredients

cetearyl alcohol, cocamidopropyl betaine, glycerin, hydrogenated castor oil, lactic acid, mineral oil, PEG-14M, potassium lauryl sulfate, potassium phosphate, purified water, silica, sodium lauryl sulfate, titanium dioxide, zeamays (corn) starch

Questions?

call 1-888-784-3335 (STIEFEL). Side effects associated with use of this product may be reported to this number.

Maximum Strength

Now you can take control of your acne with Maximum Strength PanOxyl® Acne Cleansing Bar, the highest strength of Benzoyl Peroxide (BPO) available without a prescription. The Benzoyl Peroxide in the PanOxyl® Acne Cleansing Bar is the same medicine prescribed by dermatologists.

The convenient bar form of PanOxyl® gently removes dirt and excess oil to cleanse and unclog pores, making it an excellent choice for the management of acne on the face, chest and back.

Regular Strength

Now you can take control of your acne with the PanOxyl® Acne Cleansing Bar. The 5% Benzoyl Peroxide in the PanOxyl® Acne Cleansing Bar is the same medicine prescribed by dermatologists.

The convenient bar form of PanOxyl® Acne Cleansing Bar gently removes dirt and excess oil to cleanse and unclog pores, making it an excellent choice for the management of acne on the face, chest and back.

PANOXYL is a registered trademark of Stiefel Laboratories, Inc.

www.stiefelchc.com

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Stiefel Laboratories, Inc.

Research Triangle Park, NC 27709

Relabeling by:

Physicians Total Care, Inc.

Tulsa, OK 74146

Principal Display Panel

NDC 54868-2656-0

PanOxyl®

10% Benzoyl Peroxide

Maximum Strength

ACNE CLEANSING BAR

DERMATOLOGIST Recommended Ingredients

Therapeutic acne control

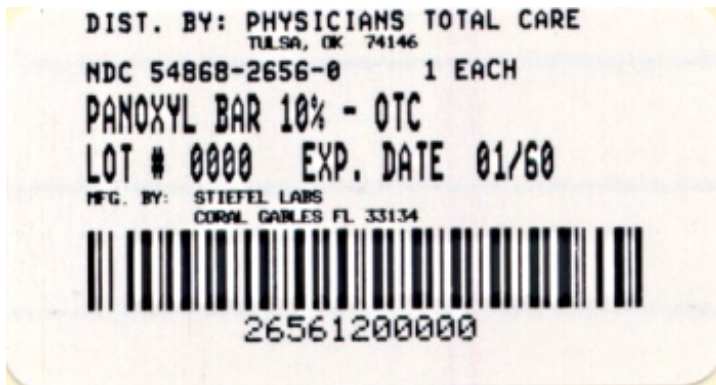
FACE

CHEST

BACK

- Benzoyl Peroxide effectively penetrates pores killing the bacteria that cause acne
- Clears existing acne blemishes and prevents new blemishes from forming

Net Wt 4 Oz (113 g)



Principal Display Panel

NDC 54868-2655-0

PanOxyl®

5% Benzoyl Peroxide

Regular Strength

ACNE CLEANSING BAR

DERMATOLOGIST Recommended Ingredients

Therapeutic acne control

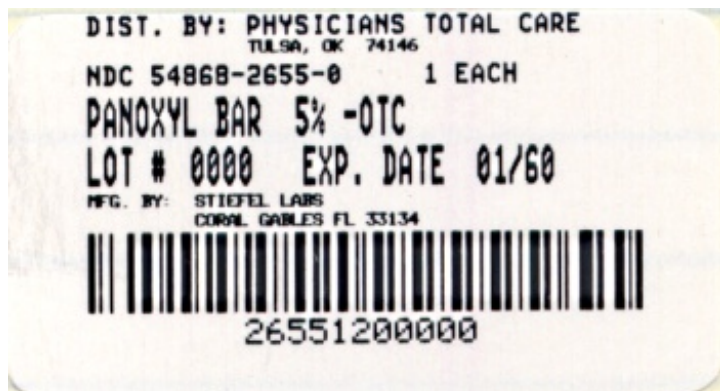
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PANOXYL

benzoyl peroxide soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54868-2656(NDC:0145-0983)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	11.3 g

Inactive Ingredients

Ingredient Name	Strength
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
LACTIC ACID (UNII: 33X04XA5AT)	
MINERAL OIL (UNII: T5L8T28FGP)	
POTASSIUM PHOSPHATE (UNII: B7862WZ632)	
WATER (UNII: 059QF0KO0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-2656-0	1 in 1 CARTON		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333D	03/31/2008	

PANOXYL

benzoyl peroxide soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54868-2655(NDC:0145-0982)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	5.65 g

Inactive Ingredients

Ingredient Name	Strength
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
LACTIC ACID (UNII: 33X04XA5AT)	
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Labeler - Physicians Total Care, Inc. (194123980)**Establishment**

Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel, repack

Revised: 5/2011

Physicians Total Care, Inc.