

PANOXYL- benzoyl peroxide soap
The Original Bradford Soap Works 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.

Panoxyl Acne Cleansing Bar

Active ingredient

Benzoyl peroxide 10%

Purpose

Acne medication

When using 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.
- 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

Stop use and ask a doctor if

- irritation becomes severe

If pregnant or breast feeding

- ask a health professional before use

Keep out of reach of children

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

Directions

- clean the skin thoroughly before applying this product
- work into a lather
- cover the entire affected area with a thin layer and rinse thoroughly one to three times daily
- pat dry

- because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three 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 20 °-25 ° (66 °-77 °F) [see USP Controlled Room Temperature].

Inactive ingredients

Aqua, Cetearyl Alcohol, Decyl Glucoside, Dextrin, Glycerin, Sodium Chloride, Sodium Cocoyl Isethionate, Tetrasodium Glutamate Diacetate

Warnings

For external use

Use**For external use only****PanOxyl® Acne Treatment Bar**

- work into a lather
- cover the entire affected area with a thin layer and rinse thoroughly one to three times daily

Package label



PANOXYL

benzoyl peroxide soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11118-0264
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZ N9A0GM) (BENZOYL PEROXIDE - UNII:W9WZ N9A0GM)	BENZOYL PEROXIDE	12.6 g in 113 g

Inactive Ingredients

Ingredient Name	Strength
ICODEXTRIN (UNII: 2NX48Z0A9G)	17.6 g in 113 g

WATER (UNII: 059QF0KO0R)	10.8 g in 113 g
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	2.7 g in 113 g
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	13.2 g in 113 g
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	0.4 g in 113 g
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.5 g in 113 g
SODIUM COCOYL ISETHIONATE (UNII: 518XTE8493)	52.2 g in 113 g
GLYCERIN (UNII: PDC6A3C0OX)	3 g in 113 g

Product Characteristics

Color		Score	
Shape	OVAL (Saddle)	Size	91mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11118-0264-4	113 g in 1 CARTON; Type 0: Not a Combination Product	06/05/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M006	06/05/2023	

Labeler - The Original Bradford Soap Works Inc (001201045)

Revised: 6/2023

The Original Bradford Soap Works Inc