

UNBLEM EST - benzoyl peroxide cream

Elli Est

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.

Active Ingredients: Benzoyl Peroxide 10%

Purpose: Acne Treatment

Keep out of reach of children: if swallowed, get medical help or contact a poison control center right away

Usage: For external use only.
Do not use if: you have very sensitive skin are sensitive to benzoyl peroxide.

Warning: For external use only.
Do not use if you- have very sensitive skin-are sensitive to benzoyl peroxide.
Keep Out of reach of children. If swallowed, get medical help or contact a poison control center right away.

When using this product -keep away from eyes, lips and mouth.-
If contact occurs, flush thoroughly with water.- If going outside apply sunscreen after using this product.

-If irritation or sensitivity develops, stop use of both products and ask a doctor.
Avoid contact with hair or dyed fabric,including carpet and clothing which may be bleached by this product.

-skin irritation may occur ,characterized by redness, burning , itching, peeling or possibly swelling.
Mild irritation may be reduced by using the product less frequently or in a lower concentration. -If irritation becomes sever, discontinue use.

If irritation still continues ,consult a doctor.

-Using other topical acne medication at the same time or immediately following the use of this product may increase dryness or irritation of the skin.

If this occurs only one medication should be used unless directed by a doctor

Directions: Cleanse the skin thoroughly before applying medication.- Cover the entire affected area with a thin layer 1 to 3 times daily.

-If bothersome dryness or peeling occurs, reduce application to once a day or every other day.

- Because of 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.

Inactive Ingredients: Water (Aqua), Polyacrylamide crosslinked 0.01-0.2 mole percent bisacrlyamid C-13-14 Isoparafin, laureth-7, Methylparaben, Propylparaben.

Elli'Est

Unblem'Est

Medicated Clarifying Lotion

With 10% Benzoyl Peroxide

1oz. / 28g.

Elli'Est™ New York

Drug Facts (continued)

Mild irritation may be reduced by using the product less frequently or in a lower concentration. •If irritation becomes severe, discontinue use; if irritation still continues, consult a doctor. •Using other topical acne medication at the same time or immediately following the use of this product may increase dryness or irritation of the skin. If this occurs, only one medication should be used unless directed by a doctor.

Inactive ingredients: Water (aqua), polyacrylamide, C13-14 Isoparaffin, Laureth-7, Methylparaben, propylparaben

Other Information: Store at controlled room temperature 15°-30°C (59°-86°F)

Directions: •Cleanse the skin thoroughly before applying medication. •Cover the entire affected area with a thin layer 1-3 times daily. •If bothersome dryness or peeling occurs, reduce application to once a day or every other day. •Because of excessive drying of 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.



Drug Facts

Active Ingredient: Benzoyl Peroxide 10% - Acne Treatment

Purpose

Warnings: For external use only.

Do not use if you •have very sensitive skin •are sensitive to benzoyl peroxide. **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

When using this product: •Keep away from eyes, lips and mouth. If contact occurs, flush thoroughly with water. •If going outside apply sunscreen after using this product. •If irritation or sensitivity develops, stop use of both products and ask a doctor. •Avoid contact with hair or dyed fabric, including carpet and clothing which may be bleached by this product. •Skin irritation may occur, characterized by redness, burning, itching, peeling, or possibly swelling.

Dist By Elli'Est
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NDC 42265-101-12

ndc42265-101-12
label image
bpo1

UNBLEM EST

benzoyl peroxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42265-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	100 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	840 mg in 1 g
POLYACRYLAMIDE (CROSSLINKED; 0.01-0.2 MOLE PERCENT BISACRYLAMIDE) (UNII: RHA9LWJ494)	30 mg in 1 g
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)	15 mg in 1 g
Laureth-7 (UNII: Z95S6G8201)	10 mg in 1 g
Methylparaben (UNII: A218C7H9T)	2.5 mg in 1 g
Propylparaben (UNII: Z8IX2SC10H)	2.5 mg in 1 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42265-101-12	28 g in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	10/25/2012	

Labeler - Elli Est (968164066)

Establishment

Name	Address	ID/FEI	Business Operations
Elli Est		968164066	manufacture(42265-101) , label(42265-101)

Revised: 9/2012

Elli Est