

RELOVOX - renewing clarifying cleanser emulsion
Transdermal Corp

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; Benzoyl Peroxide 2.5% (w/w)

Apply on the skin with a gentle massage twice a day, rinse thoroughly with hot water, pat dry with a clean towel. Children under 2 years of age, consult your doctor

Use for the management of acne and pimples and acne spots removal.

Indicated and use for the management of acne and removal of the acne spots, Apply on the skin with a gentle massage twice a day, rinse thoroughly with hot water, pat dry with a clean towel. Children under 2 years of age, consult your doctor

Keep out of reach of children, store in a cool dry place at room temperature.

Inactive Ingredients; water, Isoprpopyl Alcohol, glycerin, ethyl alcohol, staeric acid, carbomer, sodium hydroxide, cocamidopropyl betain, sodium lauryl sulfate, castor oil, glycolic acid, salicylic acid, cocoa butter, vitamin E, vitamin A, grape seeds oil.

- Ask your doctor if you using other acne medications
- Do not use if you are allergic to Benzoyl Peroxide
- Do not use in or near the eyes
- Do not use in large amount particularly over the raw surfaces or blisters

Stop use and Ask Doctors if

- Allergic reactions occurs
- Condition worsen and does not improve
- Excessive dryness and peeling of skin occurs
- itching, redness, burning , swelling or other symptoms occurs
- Keep both used and unused medicine out of the reach of children or pets
- If swallowed get medical attention right away Call your doctor immediately.

- Do not use in or near the eyes
- Do not use in large amount particularly over the raw surfaces or blisters

Stop use and Ask Doctors if

- Allergic reactions occurs
- Condition worsen and does not improve

carton.jpg

NDC 51350-005-05

Carton.jpg

Relovox

Renewing Clarifying Cleanser

Benzoyl Peroxide 2.5% w/w

Transdermal Corp
2002-B Hazel Street
Birmingham, MI 48009
(248) 341-3401

Net Wt. 50 g

Label; Drug Facts
Active Ingredient; Benzoyl Peroxide 2.5%
w/w

Renewing Clarifying Cleanser

Uses; to reduce;

- Acne
- Acne scars
- lighten areas of darkened skin caused by the blackheads
- Acne spots removal

Warnings; For external uses only

When using this product; Avoid using skin products that can cause irritation, such as harsh soaps, shampoos, or skin cleansers, hair removers or waxes, or skin products with alcohol, spices, astringents, or lime. Avoid direct sunlight and sun block agents. Do not use with other medicated skin products unless your doctor has told you to do so. Stop use and Ask Doctors if itching, redness, burning, swelling or other symptoms occurs, keep out of the reach of children or pets. If swallowed get medical attention right away, Call your doctor immediately.

Directions; Cleanse the skin with soap and warm water, pat dry, Clean your face twice a day or more as recommended by your doctor.

Storage; store at room temperature (25°C) and away from heat and light.

Inactive Ingredients; water, Isopropyl Alcohol, glycerin, ethyl alcohol, Stearic Acid, Carbomer, cocamidopropyl betain, sodium lauryl sulfate, sodium hydroxide, hydrogen peroxide, castor oil, vitamin E, vitamin A, glycolic acid, salicylic acid, grape seeds oil, EDTA, Benzyl Alcohol, Sodium Lauryl Sulfate,

Net Weight; 50 g

RELOVOX

renewing clarifying cleanser emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51350-005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	25 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)
GLYCERIN (UNII: PDC6A3C0OX)
STEARIC ACID (UNII: 4ELV7Z65AP)
SODIUM LAURYL SULFATE (UNII: 368GB5141J)
ISOPROPYL ALCOHOL (UNII: ND2M416302)
ZINC ACETATE (UNII: FM5526K07A)
ALCOHOL (UNII: 3K9958V90M)
ALOE (UNII: V5VD430YW9)
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)
GLYCOLIC ACID (UNII: 0WT12SX38S)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
CASTOR OIL (UNII: D5340Y2I9G)
SODIUM HYDROXIDE (UNII: 55X04QC32I)
SALICYL ALCOHOL (UNII: FA1N0842KB)
SALICYLIC ACID (UNII: O414PZ4LPZ)
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51350-005-06	1 in 1 CARTON		
1	NDC:51350-005-05	30 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333D	03/31/2011	

Labeler - Transdermal Corp (963383612)

Registrant - Transdermal Corp (963383612)

Establishment

Name	Address	ID/FEI	Business Operations
Transdermal Corp		963383612	manufacture, label, analysis, pack