

OXY TOTAL CARE VITAMIN C SERUM- salicylic acid solution
The Mentholatum Company

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

Salicylic acid 0.5%

Purpose

Salicylic acid – Acne treatment

Keep Out of Reach of Children

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

Uses

- For the treatment of acne.
- Helps prevent new acne blemishes.

Warnings

For external use only.

When using this product

- keep away from eyes. If contact occurs, flush thoroughly with water.
- 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.

If pregnant or breast-feeding, ask a health professional before use.

Directions

- clean the skin thoroughly before applying this product
- use one to three drops to cover the entire affected area with a thin layer one to three times daily
- 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.
- *Sensitivity Test for a New User.* Apply product sparingly to one or two small affected

areas during the first 3 days. If no discomfort occurs, follow the directions stated above.

Inactive Ingredients

water, ethoxydiglycol, butylene glycol, glycerin, disteareth-100 IPDI, 3-O-ethyl ascorbic acid [vitamin C], PEG-8 dimethicone, PEG-8 ricinoleate, citric acid, fragrance, ganoderma lucidum [mushroom] extract, hyaluronic acid, potassium sorbate, propanediol, silanetriol, sodium benzoate, xanthan gum

Questions?1-877-636-2677

MON-FRI 9AM-5PM (EST)

Package/Label Principal Display Panel

OXY Total Care Vitamin Serum



OXY TOTAL CARE VITAMIN C SERUM

salicylic acid solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10742-1315
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: 0414PZ4LPZ) (SALICYLIC ACID - UNII:0414PZ4LPZ)	SALICYLIC ACID	5 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A18X02B)	
BUTYLENE GLYCOL (UNII: 3XUS85KORA)	
GLYCERIN (UNII: PDC6A3C0OX)	
DISTEARETH-100 ISOPHORONE DIISOCYANATE (UNII: P37PW4M0IS)	
3-O-ETHYL ASCORBIC ACID (UNII: 6MW60CB71P)	
PEG-8 DIMETHICONE (UNII: GIA7T764OD)	
PEG-8 RICINOLEATE (UNII: DM36F4D2OU)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
REISHI (UNII: TKD8LH0X2Z)	
HYALURONIC ACID (UNII: S270N0TRQY)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PROPANEDIOL (UNII: 5965N8W85T)	
SILANETRIOL (UNII: E52D0J3TS5)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10742-1315-1	1 in 1 CARTON	09/30/2019	
1		37 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	09/30/2019	

Labeler - The Mentholatum Company (002105757)

Registrant - The Mentholatum Company (002105757)

Establishment

Name	Address	ID/FEI	Business Operations
The Mentholatum Company		002105757	manufacture(10742-1315)

