

TREAT SO DEEP ACNE-FIGHTING TREATMENT- salicylic acid gel
ASPIRE BRANDS 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.

ASPIRE BRANDS - FORMULA 10.0.6 TREAT SO DEEP ACNE-FIGHTING TREATMENT (70626-106)

ACTIVE INGREDIENT

SALICYLIC ACID 2%

PURPOSE

ACNE TREATMENT

USE

ACNE TREATMENT TO HELP CLEAR UP AND PREVENT NEW ACNE BLEMISHES, BLACKHEADS, AND WHITEHEADS.

WARNINGS

- FOR EXTERNAL USE ONLY
- FLAMMABLE: KEEP AWAY FROM OPEN FIRE OR FLAME.

WHEN USING THIS PRODUCT:

- AVOID CONTACT WITH 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.

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.
- COVER THE ENTIRE AFFECTED AREA WITH A THIN LAYER ONE TO THREE TIMES DAILY.
- BECAUSE EXCESSIVE DRYING OF THE SKIN MAY OCCUR, START WITH ONCE A DAY, THEN GRADUALLY INCREASE TO TWO 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: WE RECOMMEND A PATCH TEST BEFORE ADDING A NEW PRODUCT TO YOUR SKIN CARE ROUTINE. APPLY A SMALL AMOUNT OF PRODUCT TO FRESHLY CLEANSED SKIN SUCH AS THE UNDERSIDE OF YOUR WRIST, JAW/NECK LINE OR BEHIND THE EAR. LEAVE FOR 24 HOURS AND CHECK FOR ANY ADVERSE REACTION.

INACTIVE INGREDIENTS

ALCOHOL DENAT., ALLANTOIN, BISABOLOL, BUTYLENE GLYCOL, CAPRYLYL GLYCOL, CARBOMER, CITRIC ACID, DIMETHYL ISOSORBIDE, DISODIUM EDTA, GLYCERIN, HYDROXYETHYLCELLULOSE, NORDIHYDROGUAIARETIC ACID, OLEANOLIC ACID, PEG-60 ALMOND GLYCERIDES, PEG-40 HYDROGENATED CASTOR OIL, PEG-8/SMDI COPOLYMER, SACCHARIDE ISOMERATE, SODIUM CITRATE, SODIUM HYDROXIDE, TETRAHEXYLDECYL ASCORBATE, WATER.

QUESTIONS/COMMENTS:

1-866-984-1433

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: 0414PZ4LPZ) (SALICYLIC ACID - UNII:0414PZ4LPZ)	SALICYLIC ACID	2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
ALLANTOIN (UNII: 344S277G0Z)	
.ALPHA.-BISABOLOL, (+)- (UNII: 105S6I733Z)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
NORDIHYDROGUAIARETIC ACID, (+/-)- (UNII: 7PZ73W4ZNR)	
OLEANOLIC ACID (UNII: 6SMK8R7TGJ)	
PEG-60 ALMOND GLYCERIDES (UNII: 4Y0E651N0F)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
PEG-8/SMDI COPOLYMER (UNII: CCX72L6NY6)	
SACCHARIDE ISOMERATE (UNII: W8K377W98I)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70626-106-15	1 in 1 BOX	12/05/2020	
1		15 mL in 1 TUBE; 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	12/05/2020	

Labeler - ASPIRE BRANDS INC (832462811)