ANTI ACNE CALMING CORRECTOR - salicylic acid gel H2O Plus

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 1.5%

Purpose acne treatment

Warnings For external use only.

Ask a doctor of pharmacist before use if you are using other topical acne medications at the same time or immediately following use of this product. This may increase dryness or irritation of skin. If this occurs, only one medication should be used unless directed by a doctor.

When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. If excessive skin irritation develops or increases, discontinue use and consult a doctor.

Directions

Cleanse the skin thoroughly before applying medication. • 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.

Inactive Ingredients

Water (Aqua), SD Alcohol 40-B, Hamamelis Virginiana (Witch Hazel) Bark/Leaf/Twig Extract, Butylene Glycol, Glycerin, Glycolic Acid, Sodium Lactate, Linoleamidopropyl PG-Dimonium Chloride Phosphate, Hydroxyethylcellulose, Sodium Hydroxide, Fragrance (Parfum), Polysorbate 20,

Polyquaternium-10, Hydrolyzed Algin, Linalool, Propylene Glycol, Sea Salt (Maris Sal), Palmaria Palmata Extract, Crithmum Maritimum Extract, Himanthalia Elongata Extract, Gigartina Stellata Extract, Macrocystis Pyrifera Extract, Zinc Sulfate

Questions? call 1-800-242-2284 M-F, 8am-6pm CST

picture of carton label aacc272.jpg

Drug Facts

Active Ingredient Purpose Salicylic Acid 1.5%....acne treatment

Uses

- Treats acne
- · Dries up acne blemishes
- Helps prevent the development of new acne blemishes

Warnings For external use only.

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anti-acne calming corrector (salicylic acid acne treatment)

(corrector calmant) tratamiento del acné con ácido salicífico (correcteur apaisant) traitement pour peaux acnéiques à l'acide salicylique

Suntrum Alert: This product contains an alpha hydroxy acid (AHA), which may increase your skin's sensitivity to the sun and particularly the possibility of suntrum. Use a sunscreen, wear protective coldring and limit sun exposure while using this product and for a week afterward.

C2010 H2O PLUS CHICAGO, IL 60607 To order: call 1-800-242-2284 or shop online at h2oplus.com Against animal testing. Please recycle. MADE IN U.S.A. 083-00272-000 272

.85 fl oz • 25 mL

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ANTI ACNE CALMING CORRECTOR

salicylic acid gel

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:65903-272

Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Salicylic Acid (UNII: O414PZ4LPZ) (Salicylic Acid - UNII:O414PZ4LPZ)	Salicylic Acid	15 uL in 1 mL	

Inactive Ingredients	
Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
HAMAMELIS VIRGINIANA BARK (UNII: IH3063S9MY)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCOLIC ACID (UNII: 0WT12SX38S)	
SODIUM LACTATE (UNII: TU7HW0W0QT)	
LINO LEAMIDO PRO PYL PG-DIMO NIUM CHLO RIDE PHO SPHATE (UNII: 5Q87K461JO)	
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)	
SO DIUM HYDRO XIDE (UNII: 55X0 4QC32I)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POLYQUATERNIUM-10 (400 CPS AT 2%) (UNII: HB1401PQFS)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SEA SALT (UNII: 87GE52P74G)	
DULSE (UNII: 7832HO Y4ZQ)	
CRITHMUM MARITIMUM (UNII: J7IHY79BKY)	
HIMANTHALIA ELO NGATA (UNII: 21RND18 XRR)	
MASTO CARPUS STELLATUS (UNII: 6T087FC66H)	
MACRO CYSTIS PYRIFERA (UNII: K31S3OG5C4)	
ZINC SULFATE (UNII: 89DS0H96TB)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:65903-272-02	1 in 1 CARTON		
1 NDC:65903-272-01	25 mL in 1 BOTTLE, PUMP		

Marketing Info	rmation		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	0 3/0 1/20 10	

Labeler - H2O Plus (807722947)

Registrant - H2O Plus (807722947)

Establishment

Name	Address	ID/FEI	Business Operations
H2O Plus		807722947	manufacture

Revised: 9/2011 H2O Plus