ADVANCED ACNE SPOT TREATMENT CVS- salicylic acid 2.00% lotion CVS

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 ingredient

Purpose

Salicylic Acid – 2.00%

Acne Medication

Use

For treatment of acne

Warnings

For external use only

IFlammable. Keep away from fire or flame.

When using this product and other topical acne medications at the same time or immediately following use of this product, increased dryness or irritation of the skin may occur. If this occurs, only one medication should be used unless directed by a doctor.

Keep out of reach of the children

If product is swallowed, get medical help or contact a Poison Control Center right away. Avoid contact with eyes. If contact occurs, flush thoroughly with water

Directions []• cleans the skin thoroughly before applying medication • cover the entire affected area with a thin layer one to three times a day • If bothersome dryness or peeling occurs, reduce application to once a day or every other day. • Recomended for daily use.

Inactive ingredients :Water, Alcohol, Hamamelis Virginiana (Witch Hazel) Extract, Glycerin, C13-14 Isoparaffin, Laureth-7, Polyacrylamide

C12-15 Alkyl Lactate, Cetyl Lactate, Cedrus Atlantica Bark Extract, Cinnamomum Zeylanicum Bark Extract, Butylene Glycol, Dimethicone, Capryloyl Glycine, Ammonium Hydroxide, Portulaca Oleracea Extract, Benzalkonium Chloride, Propylene Glycol, Cocamidopropyl PG-Dimonium, hloride Phosphate, Cyclopentasiloxane, Phenoxyethanol, Dehydroxanthan Gum, Denatonium Benzoate, Fragrance, Hexylene Glycol, Polysorbate 20, PPG-2 Isoceteth-20 Acetate, Sarcosine, t-Butyl Alcohol, Tetrasodium EDTA



CVS Health™ Advanced Acne Spot Treatment works to help reduce acne pimples.

Drug Facts

Active ingredient

Purpose

Salicylic Acid 2.0%......Acne Medication

Use . For the treatment of acne

Warnings

For external use only,

Flammable, keep away from open fire or flame

When using this product and other topical acne medication at the same time or immediately following use of this product, increased dryness or imitation of the skin may occur. If this occurs, only one medication should be used unless directed by a doctor.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. Avoid contact with eyes. If contact occurs, flush thoroughly with water.

Directions • Cleanse 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 usage to once a day or every other day. • Recommended for daily use.

Inactive ingredients Water, Alcohol, Hamamells Virginiana (Witch Hazel) Extract, Glycerin, C13-14 Isoparaffin, Laureth-7, Polyacrylamide, C12-15 Alkyl Lactate, Cetyl Lactate, Cedrus Atlantica Bark Extract, Cinnamomum Zeylanicum Bark Extract, Butylene Glycol, Dimethicone, Capryloyl Glycine, Ammonium Hydroxide, Portulaca Oleracea Extract, Benzalkonium Chloride, Propylene Glycol, Cocamidopropyl PG-Dimonium Chloride Phosphate, Cyclopentasiloxane, Phenoxyethanol, Dehydroxanthan Gum, Denatonium Benzoate, Fragrance, Hexylene Glycol, Polysorbate 20, PPG-2 Isoceteth-20 Acetate, Sarcosine, t-Butyl Alcohol, Tetrasodium EDTA.

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Made in the U.S.A. of U.S. and imported components V-12412



ADVANCED ACNE SPOT TREATMENT CVS

salicylic acid 2.00% lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-343
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Salicylic Acid (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	Salicylic Acid	2 g in 100 mL	

Inactive Ingredients	
Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Alcohol (UNII: 3K9958V90M)	
HAMAMELIS VIRGINIANA TOP WATER (UNII: NT00Y05A2V)	
Glycerin (UNII: PDC6A3C0OX)	
C13-14 Isoparaffin (UNII: E4F12ROE70)	
Laureth-7 (UNII: Z95S6G8201)	
C12-15 Alkyl Lactate (UNII: GC844VRD7E)	
Cetyl Lactate (UNII: A7EVH2RK4O)	
CEDRUS ATLANTICA BARK (UNII: ITP1Q41UPF)	
CINNAMON BARK OIL (UNII: XE54U569EC)	
Butylene Glycol (UNII: 3XUS85K0RA)	
Capryloyl Glycine (UNII: 8TY5YO42NJ)	
AMMO NIA (UNII: 5138 Q 19 F1X)	
PURSLANE (UNII: M6S840WXG5)	
Benzalkonium Chloride (UNII: F5UM2KM3W7)	
Propylene Glycol (UNII: 6DC9Q167V3)	
CYCLOMETHICONE 5 (UNII: 0 THT5PCI0 R)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Dehydroxanthan Gum (UNII: 63ZP7I1BQO)	
Denatonium Benzoate (UNII: 4YK5Z54AT2)	
Polysorbate 20 (UNII: 7T1F30V5YH)	
PPG-2 Isoceteth-20 Acetate (UNII: BI6C7YO419)	
Sarcosine (UNII: Z711V88R5F)	
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	
EDETATE SO DIUM (UNII: MP1J8420LU)	
COCAMIDO PRO PYL PRO PYLENE GLYCOL-DIMO NIUM CHLO RIDE PHO SPHATE (UNII: H2KVQ 74JM4)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:59779-343-01	1 in 1 CARTON	12/22/2014	
1	22 mL in 1 TUBE; Type 0: Not a Combination Product		

	Marketing Infor	rmation		
l	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph final	part333D	12/22/20 14	

Labeler - CVS (062312574)

Registrant - Product Quest Mfg. (927768135)

Establishment			
Name	Address	ID/FEI	Business Operations
Product Quest Mfg.		927768135	manufacture(59779-343), label(59779-343)

Revised: 12/2017 CVS