CRYSTAL CLEAR ACNE TREATMENT PADS- salicylic acid patch Skin Pharm, LLC

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.

CRYSTAL CLEAR Salicylic Acid Acne Treatment Pads

Drug Facts

Active ingredient

Salicylic acid 2% w/v

Purpose

Acne treatment

Use

for the treatment of acne

Warnings

For external use only

When using this product • 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 • avoid contact with eyes, lips and mouth. If contact occurs, flush thoroughly with water.

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 one to two times daily, avoiding eye area allow to absorb before applying additional products because excessive drying of the skin may occur, start with one application daily, 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 do not rinse tighten cap after use to prevent pads from drying out.
- Sensitivity Test for a New User. Apply product sparingly to one or two small affected areas during the first three days. If no discomfort occurs, follow the directions stated above.

Other information

- store at 68° 77° F protect from excessive moisture
- Sunburn Alert: This product contains an alpha hydroxy acid (AHA) that may increase your skin's sensitivity to the sun and particularly the possibility of sunburn. Use a sunscreen, wear protective clothing and limit sun exposure while using this product and for a week afterwards.

Inactive ingredients

Allantoin, Aloe (*Aloe barbadensis*) leaf extract, Beta-glucan, Caprylic/capric triglyceride, Chamomile (*Chamomilla recutita*) flower extract, Cucumber (*Cucumis sativus*) fruit extract, Dipotassium glycyrrhizate, Ethoxydiglycol, Ethylhexylglycerin, Glycerin, Glycolic acid, Grapefruit (*Citrus grandis*) peel extract, Lactic acid, Licorice (*Glycyrrhiza glabra*) root extract, Menthyl lactate, PEG-40 hydrogenated castor oil, Phenoxyethanol, PPG-26-Buteth-26, Sodium hydroxide, Tetrasodium EDTA, Water (Aqua), White mulberry (*Morus alba*) root extract

Questions?

+1-615-582-6726

You may also report serious side effects to this phone number.

Mon - Fri, 9:30 AM - 5:30 PM

Manufactured for Skin Pharm, Nashville, TN 37212

skinpharm.com

Packaging

Drug Facts (continued)

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SKINPHARM

CRYSTAL CLEAR

Salicylic Acid Acne **Treatment Pads**

60 pads

Use for the

Active ingredient

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Drug Facts (continued)

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DRUG FACTS TABLE

Drug Facts

Active ingredient

Purpose

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..Acne treatment

Use for the treatment of acne

Warnings

For external use only

When using this product • 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 avoid contact with with eyes, lips and mouth. If contact occurs, flush thoroughly with water.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Drug Facts (continued)

Directions • clean the skin thoroughly before applying this product • cover the entire affected area one to two times daily, avoiding eye area • allow to absorb before applying additional products • because excessive drying of the skin may occur, start with one application daily, 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 • do not rinse • tighten cap after use to prevent pads from drying out.

Sensitivity Test for a New User. Apply product sparingly to one or two small affected areas during the first three days. If no discomfort occurs, follow the directions stated above.

Other information • store at 68° - 77° F • protect from excessive moisture

Drug Facts (continued)

• Sunburn Alert: This product contains an alpha hydroxy acid (AHA) that may increase your skin's sensitivity to the sun and particularly the possibility of sunbum. Use a sunscreen, wear protective clothing and limit sun exposure while using this product and for a week afterwards.

Inactive ingredients Allantoin, Aloe (Aloe barbadensis) leaf extract, Beta-glucan, Caprylic/capric triglyceride, Chamomile (Chamomilla recutita) flower extract, Cucumber (Cucumis sativus) fruit extract, Dipotassium glycyrrhizate, Ethoxydiglycol, Ethylhexylglycerin, Glycerin, Glycolic acid, Grapefruit (Citrus grandis) peel extract, Lactic acid, Licorice (Glycyrrhiza glabra) root extract, Menthyl lactate, PEG-40 hydrogenated castor oil, Phenoxyethanol, PPG-26-Buteth-26, Sodium hydroxide, Tetrasodium EDTA, Water (Aqua), White mulberry (Morus alba) root extract

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Manufactured for Skin Pharm, Nashville, TN 37212

CRYSTAL CLEAR ACNE TREATMENT PADS

salicylic acid patch

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:83316-001

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		
ALLANTOIN (UNII: 344S277G0Z)			
ALOE VERA LEAF (UNII: ZY81Z83H0X)			
YEAST .BETAD-GLUCAN (UNII: 44FQ49X6UN)			
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)			
CHAMOMILE (UNII: FGL3685T2X)			
CUCUMBER (UNII: YY7C30VXJT)			
GLYCYRRHIZINATE DIPOTASSIUM (UNII: CA2Y0FE3FX)			
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A118X02B)			
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)			
GLYCERIN (UNII: PDC6A3C0OX)			
GLYCOLIC ACID (UNII: 0WT12SX38S)			
CITRUS MAXIMA FRUIT RIND (UNII: 5NX3G75CA6)			
LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)			
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)			
MENTHYL LACTATE, (-)- (UNII: 2BF9E65L7I)			
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)			
PHENOXYETHANOL (UNII: HIE492ZZ3T)			
PPG-26-BUTETH-26 (UNII: 2II1K6TZ4P)			
SODIUM HYDROXIDE (UNII: 55X04QC32I)			
EDETATE SODIUM (UNII: MP1J8420LU)			
WATER (UNII: 059QF0KO0R)			
MORUS ALBA ROOT (UNII: CST1G9BZGD)			

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:83316-001- 01	60 in 1 JAR	02/16/2023				
1		1.2 mL in 1 PATCH; Type 0: Not a Combination Product					

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	M006	02/16/2023				

Labeler - Skin Pharm, LLC (040717587)

Revised: 3/2023 Skin Pharm, LLC