ZAPNE- salicylic acid 0.5% cloth Zapne 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.

ZAPNE PRODUCT OTC DRUG LABEL

Directions:

- Wash skin to remove dirt, oils, and any cosmetics or lotions, then dry thoroughly.
- Open ZAPNE Packet Part 1 Towelette infused with natrual 0.5% salicylic acid and thoroughly wipe face and neck. Allow to dry and do not rinse.
- Open Zapne Packet part 2-A which contains a green/gray powder of natrual fresh water sponge (spongilla lacustris), natural Aloe Vera, natrual sericin, brown seaweed, organic green tea, organic ginger root, willow bark, and chamomile. Pour its contens into a small mixing bowl.
- Carefully open ZAPNE Packet Part 2-B consisting of hydrogen peroxide 3% and water. Pour its content into a mixing bowl containing the powder.
- Mix thoroughly using your finger (1 minute).
- Apply the ZAPNE mixture as a max over your entire face. Rub vigorously with your fingers, according to your skin sensitivity. Massage in small circular motions. Avoid applying the mask too close to the eyes.
- Allow to drive for about 15 minutes. A tingling sensation may be felt as the mask begins drying and the skin may experience erythema (slight redness),
- Next rinse skin thoroughly by splashing cold water or showering to remove the mask. Do not wipe or scrub face.
- Any skin erythema (slight redness) and tingling sensations gradually fade over 8-24 hours.
- For best results avoid heavy moisturizers for at least 12 hours .
- After skin starts sloughing (shedding) within 3-4 days, scrub your face using an exfoliating scrub, cloth, or loofa to remove any dead skin.
- Avoid direct sunlight for two weeks after using the mask. Use a sunscreen if it is necessary to be in direct sunlight.
- Apply again one week after the first application and contine to apply weekly until the desired results are acheived.

WARNING: Avoid direct contact with eyes. If contact occurs, rinse thoroughly with water or other eye wash fuilds. If the problem persists, see a doctor immediately.

Directions: Wash skin to remove dirt, oils, and any cosmetics or lotions, then dry thoroughly. Open ZAPNE Packet Part 1 - Towelette infused with natural 0.5% salicylic acid and thoroughly wipe face and neck. Allow to dry and do not rinse. Open ZAPNE Packet Part 2-A which contains a green/gray powder of natural fresh water sponge (spongilla lacustris), natural Aloe Vera, natural sericin brown seaweed, organic green tea, organic ginger root, willow bark, and chamomile. Pour its contents into a small mixing bowl. Carefully open ZAPNE Packet Part 2-B consisting of hydrogen peroxide 3% and water. Pour its contents into the mixing bowl containing the powder. Mix thoroughly using your finger (1 minute). Apply the ZAPNE mixture as a mask over your entire face. Rub vigorously with your fingers, according to your skin sensitivity. Massage in small circular motions. Avoid applying the mask too close to the eyes. Allow to dry for about 15 minutes. A tingling sensation may be felt as the mask begins drying and the skin may experience erythema (slight redness). Next rinse skin thoroughly by splashing cold water or showering to remove the mask. Do not wipe or scrub face. Any skin erythema (slight redness) and tingling sensations gradually fade over 8-24 hours. For best results avoid heavy moisturizers for at least 12 hours. After skin starts sloughing (shedding) within 3-4 days, scrub your face using an exfoliating scrub, cloth, or loofa to remove any dead skin. Avoid direct sunlight for two weeks after using the mask. Use a sunscreen if it is necessary to be in direct sunlight. Apply again one week after the first application and continue to apply weekly until desired results are achieved. WARNING: Avoid direct contact with eyes. If contact occurs, rinse thoroughly with water or other eye wash fluids. If the problem persists, see a doctor immediately .

Using other topical acne medications at the same time or immediately following the use of this product may increase dryness or irritation of the skin. If this occurs, only one treatment should be used unless directed by a doctor. Avoid direct contact with eyes. If contact occurs, rinse thoroughly with water.

Keepy out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

ZAPIE

ACNE TREATMENT SYSTEM

Active ingredients

Salicylic Acid 0.5% from Natural Willow Bark Extract

Indications

For the treatment of Acne

Other Ingredients

Natural Fresh Water Sponge (Spongilla lacustris), Organic Aloe Vera, Natural Sericin, Brown Seaweed, Organic Green Tea, Organic Ginger Root, Willow Bark (Salix alba), Organic Chamomile, Propanediol, Decyl Glucoside, Citric Acid, Potassium Sorbate, Hydrogen Peroxide and Water.

Store above freezing and below 100°F

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Does Not Contain: Benzoyl Peroxide, Parabens, Phthalates, Sodium Lauryl/Laureth Sulfate, Sodium Methyl Sulfate, Artificial Colors or Fragrances

Questions? Visit www.zapne.com or call toll-free 866-924-1003 or 702-861-0047

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Zapne

Acne Treatment System

- Use Only Once a Week
- Easy 15-minute Mask Treatment
- Fast Acting
- Feel and See it Working
- All NAtrual Ingredients
- Four Complete Weekly Treatments

ACNE TREATMENT SYSTEM » Use Only Once a Week » Easy 15-minute Mask Treatment Fast Acting Feel and See it Working » All Natural Ingredients Four Complete Weekly Treatments The ZAPNE 2 Part Treatment System consists of Part 1. Medicated Towelette, infused with natural salicylic acid which is applied to the skin first, followed by applying a mask made by mixing Parts 2-A and 2-B. Apply the mask to the skin using your fingers and allow to dry for 15 minutes. Then rinse and let ZAPNE zap your acne. For more information, SCAN Ø É

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active salicylic acid 0.5% from natural willow bark extract Indications For the treatment of Acne

Natural Fresh Water Sponge(spongilla

lacustris), organic Aloe Vera,

Natural

Sericin, Brown Seaweed, Organic

Green

Ingredients

Other

Tea, Organic Ginger Root, Willow

Bark

(Salix alba), Organic Chamomile, Propanediol, Decyl Glucoside,

Citric

Acid, Potassium Sorbate, Hydrogen

Peroxide and Water

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ZAPNE

salicylic acid 0.5% cloth

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71024-105

Route of Administration CUTANEOUS

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	20 mg in 1300 mg

Inactive Ingredients			
Ingredient Name	Strength		
SPONGILLA LACUSTRIS (UNII: 6SZ0G98BHM)	1261 mg in 1300 mg		
SILK SERICIN (UNII: 0N1VMU8G9W)	1.08 mg in 1300 mg		
NORI (UNII: 477TV3P5UX)	1.08 mg in 1300 mg		
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	1.08 mg in 1300 mg		
GINGER (UNII: C5529G5JPQ)	1.08 mg in 1300 mg		
WILLOW BARK (UNII: S883J9JDYX)	1.08 mg in 1300 mg		
CHAMO MILE (UNII: FGL3685T2X)	1.08 mg in 1300 mg		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	325 mg in 1300 mg		

	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:71024-105-11	1 in 1 BOX	10/01/2014	
ı	1	4 mg in 1 PACKET; 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	10/01/2014	

Labeler - Zapne LLC (080395104)

Registrant - Zapne LLC (080395104)

Establishment			
Name	Address	ID/FEI	Business Operations
Zapne LLC		080395104	repack(71024-105), pack(71024-105), manufacture(71024-105), label(71024-105)

Revised: 10/2016 Zapne LLC