

MIZON ACENCE BLEMISH OUT PINK SPOT- salicylic acid solution
MIZON CO., LTD.

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

Active Ingredient: Salicylic Acid 0.5%

INACTIVE INGREDIENT

Inactive Ingredients: Alcohol, Water, Calamine, Glycerin, Titanium Dioxide(CI77891), Glycolic Acid, Dimethyl Sulfone, Camphor, Peg-60 Hydrogenated Castor Oil, Rubus Idaeus(Raspberry) Fruit Extract, Propylene Glycol, Butylene Glycol, Coptis Chinensis Root Extract, Portulaca Oleracea Extract, Vaccinium Myrtillus Fruit/Leaf Extract, Saccharum Officinarum(Sugar Cane) Extract, Melaleuca Alternifolia(Tea Tree) Leaf Oil, Citrus Medica Limonum(Lemon) Fruit Extract, Citrus Aurantium Dulcis(Orange) Fruit Extract, Acer Saccharum(Sugar Maple) Extract, Pinus Pinaster Bark/Bud Extract, Hedera Helix(Ivy) Extract, Citrus Grandis(Grapefruit) Peel Oil

PURPOSE

Purpose: Blemish Treatment

WARNINGS

Warnings: 1. For external use only. 2. Avoid contact with eyes and mouth. 3. Discontinue use if signs of irritation or rashes appear. 4. Replace the cap after use. 5. If ingestion occurs, give victim water and seek medical attention.

KEEP OUT OF REACH OF CHILDREN

KEEP OUT OF REACH OF CHILDREN

Directions for use

Directions for use: Cleanse face thoroughly using face wash. Without shaking, use a cotton swab to dip to the bottom and apply directly to only blemishes and trouble spots overnight. Wash off with face wash the following morning.

DOSAGE & ADMINISTRATION

Dosage & Administration: Use on blemishes or pimples once daily. If excessive dryness or irritation occurs, discontinue use and consult your doctor.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



MIZON ACENCE BLEMISH OUT PINK SPOT

salicylic acid solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57718-060
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Salicylic Acid (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	Salicylic Acid	0.15 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
Alcohol (UNII: 3K9958V90M)	
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57718-060-01	30 mL in 1 CARTON; 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	07/01/2015	

Labeler - MIZON CO., LTD. (557815570)

Registrant - MIZON CO., LTD. (557815570)

Establishment

Name	Address	ID/FEI	Business Operations
MIZON CO., LTD.		557815570	repack(57718-060)

Establishment

Name	Address	ID/FEI	Business Operations
Coson Co., Ltd.		689835593	manufacture(57718-060)

Revised: 8/2015

MIZON CO., LTD.