

AMINO EX 500ML- salicylic acid shampoo
Kwang Duk Sin Yak 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.

Salicylic acid 0.25%

Betula Platyphylla Japonica Bark/Biota Orientalis Leaf/Camellia Sinensis Leaf/EcliptaProstrata/Houttuynia Cordata/Lonicera Caprifolium (Honeysuckle)/Luffa Cylindrica Fruit/MorusAlba Fruit/Morus Alba Bark/Morus Alba Leaf/Phellodendron Amurense Bark/PortulacaOleracea/Salvia Miltiorrhiza Root/Sophora Flavescens Extract, Angelica Gigas/Boswellia Serrata/Carthamus Tinctorius (Safflower) Flower/Citrus UnshiuPeel/Cnidium Officinale Rhizome/Commiphora Myrrha Resin/Perilla Frutescens Leaf/PolygonumMultiflorum Root Extract, Glycyrrhiza Uralensis (Licorice) Root/Lespedeza Bicolor Bark/Thuja Orientalis Seed/ViscumAlbum (Mistletoe) Extract, Water, , Sodium Laureth Sulfate, Calcium Oxide, Biotite, Cocamide DEA, Sodium Lauryl Sulfate, Cocamidopropyl Betaine, Decyl Glucoside, Glycerin, PEG-120 Methyl Glucose Dioleate, Polyquaternium-10, Purfume, Steartrimonium Chloride, L-Menthol, Arginine, Sulfur, Salicylic Acid, Dimethyl Sulfone, Sodium Benzoate

helps prevent recurrence of flaking and itching associated with dandruff on scalp

- For external use only
 - Seek medical attention if rash, inflammation, itchiness or other symptoms appear during use of the product or after exposure to direct sunlight.
 - Do not use on open wounds
 - Storage and handling precaution
1. Keep out of reach of children
 2. Store away from direct sunlight
- Rinse your eyes with water if they are exposed to the product.
 - Product may cause hair loss or discoloration if not rinsed out thoroughly.
 - Product is slippery. Clean it immediately if dropped on floor.

KEEP OUT OF REACH OF CHILDREN

For external use only

Thoroughly wet your hair and scalp.

Lather a proper amount in your palms and work into your hair and scalp. Rinse out with water. Use once a day.

salicylic acid shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71838-0010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	0.25 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
LEVOMENTHOL (UNII: BZ1R15MTK7)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71838-0010-2	1 in 1 CARTON	06/08/2020	
1	NDC:71838-0010-1	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	06/08/2020	

Labeler - Kwang Duk Sin Yak Co., Ltd. (688202646)

Registrant - Kwang Duk Sin Yak Co., Ltd. (688202646)

Establishment

Name	Address	ID/FEI	Business Operations
Kwang Duk Sin Yak Co., Ltd.		688202646	manufacture(71838-0010)

Revised: 6/2020

Kwang Duk Sin Yak Co., Ltd.