

DANDRX 1% KETOCONAZOLE ANTI-DANDRUFF- dandrux 1% ketoconazole anti-dandruff shampoo liquid
dandRX LLC

85521-001

dandRX 1% Ketoconazole Anti-Dandruff Shampoo

Active Ingredient(s)

KETOCONAZOLE 1%

Purpose

Anti-dandruff

Use

Use: for the control of the symptoms of dandruff and or seborrheic dermatitis.

Warnings

for external use only.

Do not use

Do not use on open skin wounds

When using this product avoid contact with eyes, if contact occurs. rinse eyes thoroughly with water.

Stop use and ask a doctor if condition worsens or does not improve after regular use of this product as directed.

If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

Directions: for best results, use every other day or as directed by a doctor.

- Wet hair thoroughly
- Massage a liberal amount into your scalp.
- Leave lather on scalp for several minutes
- Rinse and repeat

Other information

Other information: store at room temperature between 68-78°F(20-25°C). Do not expose to excessive heat.

Inactive ingredients

Aqua, Aloe Vera Leaf, Sodium Cocoyl Isethion-ate, Sodium Lauroyl Methyl Isethionate, Co-camidopropyl Hydroxysultaine, Oatmeal, Pan-thenol, Chamomile, Green Tea Leaf, Calendula Officinalis Flower, Glycerin, Squalane, Cocos Nucifera (Coconut) Oil, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Azadirachta Indica Flower, Leuconostoc/Radish Root Ferment Filtrate, Sodium Benzoate, Citric Acid

Package Label - Principal Display Panel

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
KETOCONAZOLE (UNII: R9400W927I) (KETOCONAZOLE - UNII:R9400W927I)			KETOCONAZOLE	1 g in 100 mL
Inactive Ingredients				
Ingredient Name				Strength
GLYCERIN (UNII: PDC6A3C0OX)				
LEUCONOSTOC/RADISH ROOT FERMENT FILTRATE (UNII: D2QHA03458)				
AQUA (UNII: 059QF0K00R)				
SODIUM COCOYL ISETHIONATE (UNII: 518XTE8493)				
SODIUM LAUROYL METHYL ISETHIONATE (UNII: II6VCD3S6R)				
COCAMIDOPROPYL HYDROXYSULTAINE (UNII: 62V75NI93W)				
OATMEAL (UNII: 8PI54V663Y)				
PANTHENOL (UNII: WW9CM0O67Z)				
CHAMOMILE (UNII: FGL3685T2X)				
GREEN TEA LEAF (UNII: W2ZU1RY8B0)				
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
COCOS NUCIFERA (COCONUT) OIL (UNII: Q9L0O73W7L)				
MELALEUCA ALTERNIFOLIA (TEA TREE) LEAF OIL (UNII: VIF565UC2G)				
AZADIRACHTA INDICA FLOWER (UNII: 3TE8A92UPM)				
SQUALANE (UNII: GW89575KF9)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
CITRIC ACID (UNII: 2968PHW8QP)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85521-001-01	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/09/2025	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug		M016	04/09/2025	

Labeler - dandRX LLC (137339129)

Establishment

Name	Address	ID/FEI	Business Operations
dandRX LLC		137339129	manufacture(85521-001)