FOAMING ANTIBACTERIAL PEAR- triclosan soap Topco Associates 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.

Drug Facts Box - Back Label

Active Ingredient

Triclosan 0.46%

Purpose

Antibacterial

Warnings

For external use only.

Stop using this product and ask doctor if

Irritation or redness develops and lasts.

Keep out of reach of children

In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.

Uses

For washing to decrease bacteria on the skin.

Directions

Pump onto dry hands, Work into a lather vigorously and rinse thoroughly.

Inactive Ingredients

Water (Aqua), Sodium Xylene Sulfonate, Dipropylene Glycol, Glycerin, Sodium PCA, Ammonium Lauryl Sulfate, Cocamidopropyl Betaine, Polyquaternium-10, Fragrance (Parfum), Disodium Phosphate, Cetyl Alcohol, Aloe Barbadensis Leaf Juice, Citric Acid, Methylparaben, Propylparaben, Green 3 (CI 42053), Yellow 10 (CI 47005)

PACKAGE FRONT AND BACK LABELS

7.5OZ Front and Back Labels: tc8.jpg





FOAMING ANTIBACTERIAL PEAR

triclosan soap

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:36800-163

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthTRICLOSAN (UNII: 4NM5039 Y5X) (TRICLOSAN - UNII:4NM5039 Y5X)TRICLOSAN0.4600 mL in 100.0000 mL

Packaging

# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:36800-163-08	222 mL in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/26/2010	

Labeler - Topco Associates LLC (006935977)

Revised: 7/2010 Topco Associates LLC