

JABONITO FRESH- triclosan soap
Industria LA Popular SA

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.

PURPOSE

Antibacterial

For washing to decrease bacteria on the skin.

ACTIVE INGREDIENT

Triclosan 0.05%

WARNING

For external use only

WHEN USING THIS PRODUCT

Avoid contact with eyes. If contact occurs rinse thoroughly with water.

STOP USE and contact doctor if irritation and redness develops.

KEEP OUT OF REACH OF CHILDREN

If swallowed, get medical help or contact poison control center right away.

DIRECTIONS

Wet bar with water.

Lather vigorously and wash skin.

Rinse and dry thoroughly.

INACTIVE INGREDIENTS

Titanium Dioxide

Water

Talc

Fragrance

Sodium Tallowate

FD & C Blue No.1

OTHER INFORMATION

Registro sanitario: Guatemala PT-66360

QUESTIONS?

1-801-0026-227

Dosage and Administration

Dosage and administration

DRUG FACTS	
Active ingredient Triclosan 0.05%	Purpose Antibacterial
Uses For washing to decrease bacteria on the skin.	
Warnings For external use only. When using this product: <ul style="list-style-type: none"> Avoid contact with eyes. If contact occurs, rinse thoroughly with water. Stop use and ask a doctor if: irritation and redness develops. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions Wet bar with water. Rinse and dry thoroughly.	Lather vigorously and wash skin.
Other information ■ Registro Sanitario: Guatemala PT-66360.	
Inactive Ingredient FD&C Blue No. 1, Fragrance, Sodium Tallowate, Talc, Titanium Dioxide, Water.	
Questions? 1-801-0026227	

JABONITO FRESH

triclosan soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62476-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	0.0005 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM TALLOWATE, BEEF (UNII: 07RIK6QMEW)	
TALC (UNII: 7SEV7J4R1U)	
ABRONIA FRAGRANS WHOLE (UNII: LXC8S3ELIE)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62476-100-01	4 g in 1 BOX; Type 0: Not a Combination Product	01/26/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	01/26/2016	

Labeler - Industria LA Popular SA (846044576)

Establishment

Name	Address	ID/FEI	Business Operations
Industria LA Popular SA		846044576	manufacture(62476-100)

Revised: 2/2016

Industria LA Popular SA