

TINTURA DE ARNICA- isopropyl alcohol and arnica extract solution
Dannso Corp./d.b.a. Essential Products

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.

Arnica Tincture

☐Active Ingredients

Purpose

Isopropyl Alcohol 63-69% by Volume..... Antiseptic

☐Use

May help prevent skin infection in

- minor cuts
- scrapes
- burns
- bruises

☐Keep out of reach of children. ☐If swallowed, get medical help or contact a Poison Control Center right away.

Antiseptic

☐For External Use Only

☐Directions

- clean the affected area
- and dry thoroughly. Apply a thin layer 1 to 3 times daily.
- May be covered with a sterile bandage, let dry first.

☐Warnings☐ For external use only

Avoid Contact with eyes.

☐When using this product

- do not use on irritated skin, in or near eyes or mucous membranes, on wounds or damaged skin, if prone to allergic reaction
- Fatal if swallowed.

☐Stop use and ask a doctor if☐ condition persists or gets worse

☐Inactive Ingredients☐ Arnica Extract, Isopropyl Alcohol, Deionized Water



TINTURA DE ARNICA

isopropyl alcohol and arnica extract solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70242-129
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	0.13 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70242-129-01	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/08/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/01/2015	

Labeler - Danso Corp./d.b.a. Essential Products (059741071)

Registrant - Daniso Corp./d.b.a. Essential Products (059741071)

Establishment

Name	Address	ID/FEI	Business Operations
Daniso Corp./d.b.a. Essential Products		059741071	LABEL(70242-129)

Establishment

Name	Address	ID/FEI	Business Operations
World Perfume, Inc		10 1312044	MANUFACTURE(70242-129)

Revised: 6/2016

Daniso Corp./d.b.a. Essential Products