ROYAL ALCOHOL CLEANSING- isopropyl alcohol patch Filo America

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.

Royal Alcohol Cleansing pads

Drug Facts

Active Ingredient

Isopropyl Alcohol, 70% v/v

Purpose

Antiseptic

Use

for the preparation of skin prior to an injection to decrease germs in minor cuts and scrapes.

Warning:

For external use only

Keep out of reach of children.

If swallowed, get medical help or contact a poison control center immediately.

Caution do not apply to irritated skin.

Do not ues

in the eyes or on mucous membranes. In case of deep cuts or puncture wounds, consult a doctor.

Directions

wipe injection site vigorously.

Other information

store at room temperature.

Inactive ingredient

water.

Package Labeling:



<text><text><text><text><text><text>

ROYAL ALCOHOL CLEANSING isopropyl alcohol patch										
Product Information										
Product Type				HUMAN OTC DRUG Item Code (Sour			ource)	NDC:50435-200		
Route of Administration				TOPICAL						
Active Ingredient/Active Moiety										
Ingredient Name								Basis of Strength		
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)							ISOPROPYL	ALCOHOL	70 g in 100 g	
Inactive Ingredients										
Ing				redient Name				Strength		
WATER (UNII: 059QF0KO0R)										
Packaging										
#	ltem Code		F	Package Description		Marketing Start Date		larketing End Date		
1	NDC:50435- 200-00	100 i	n 1 BOX				11/13/2017			
1		5 g ir Devic	n 1 PATCH; Ty e/System (sy	ype 2: Prefilled Drug Delivery yringe, patch, etc.)						
Marketing Information										
Marketing Application Number or Monograph Marketing Start Marketing									oting End	
Category			Аррпса	Citation		Date		Mark	Date	
OTC monograph not final			part333A			11/11/2017				

Revised: 3/2023

Filo America

Labeler - Filo America (943873703)