

ALCOHOL PREP PAD- isopropyl alcohol swab
Foshan Flying Medical Products Co., Ltd.

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.

ALCOHOL PREP PAD

DRUG FACTS

 <p>The image shows the packaging for an Alcohol Prep Pad. It features a blue circular logo with a white cross in the center. The text "BE SMART" is at the top of the circle and "GET PREPARED" is at the bottom. Below the logo, the words "Alcohol Prep Pad" are written in a large, bold, blue font. Underneath that, it says "1 Medium Pad" and "TRI". At the bottom left, there are two small circular icons, one with a person and one with a checkmark. Below these icons, it says "Dist. By: Total Resources Int'l • Walnut, CA 91789", "Made in China", and "REORDER NO: 00-ALC-90730". At the bottom right, it says "NDC 54429-0101-6".</p>	<table border="1"><thead><tr><th colspan="2">Drug Facts</th></tr><tr><th>Active Ingredients</th><th>Purpose</th></tr></thead><tbody><tr><td>Isopropyl Alcohol 70%.....</td><td>Antiseptic Cleanser</td></tr><tr><td colspan="2">Use For preparation of the skin prior to an injection</td></tr><tr><td colspan="2">Warnings</td></tr><tr><td colspan="2">• For external use only</td></tr><tr><td colspan="2">• Flammable, keep away from fire or flame</td></tr><tr><td colspan="2">Do Not Use • with electrocautery procedures</td></tr><tr><td colspan="2">• In the eyes. If contact occurs, flush eyes with water</td></tr><tr><td colspan="2">Stop Use If irritation and redness develop. If condition persists consult your health care practitioner.</td></tr><tr><td colspan="2">Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away.</td></tr><tr><td colspan="2">Directions</td></tr><tr><td colspan="2">• Wipe injection site vigorously and discard</td></tr><tr><td colspan="2">Other Information</td></tr><tr><td colspan="2">Store at room temperature 15° - 30° C (59° - 86° F)</td></tr><tr><td colspan="2">Inactive Ingredient purified water</td></tr></tbody></table>	Drug Facts		Active Ingredients	Purpose	Isopropyl Alcohol 70%.....	Antiseptic Cleanser	Use For preparation of the skin prior to an injection		Warnings		• For external use only		• Flammable, keep away from fire or flame		Do Not Use • with electrocautery procedures		• In the eyes. If contact occurs, flush eyes with water		Stop Use If irritation and redness develop. If condition persists consult your health care practitioner.		Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away.		Directions		• Wipe injection site vigorously and discard		Other Information		Store at room temperature 15° - 30° C (59° - 86° F)		Inactive Ingredient purified water	
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ACTIVE INGREDIENT



PURPOSE

Antiseptic

Keep out of reach of children

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

USE

For preparation of the skin prior to an injection

WARNINGS

For external use only.

Flammable, keep away from fire or flame.

DIRECTIONS

Wipe injection site vigorously

INACTIVE INGREDIENT

Water

<p>ALCOHOL PREP PAD isopropyl alcohol swab</p>
<p>Product Information</p>

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54429-0101
Route of Administration	Topical		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54429-0101-1	1.4 mL in 1 POUCH		
2	NDC:54429-0101-2	14 mL in 1 KIT		
3	NDC:54429-0101-3	2.8 mL in 1 KIT		
4	NDC:54429-0101-6	1.4 mL in 1 POUCH		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	12/26/2012	

Labeler - Foshan Flying Medical Products Co., Ltd. (527021584)

Registrant - Foshan Flying Medical Products Co., Ltd. (527021584)

Establishment

Name	Address	ID/FEI	Business Operations
Foshan Flying Medical Products Co., Ltd.		527021584	manufacture(54429-0101)

Revised: 5/2014

Foshan Flying Medical Products Co., Ltd.