# BERKLEY JENSEN- witch hazel liquid TSM ITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI

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.

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### Berkley Jensen Witch Hazel

**Drug Facts** 

#### **Active Ingredient**

Witch Hazel-----86%

#### **Purpose**

Astringent

#### **Indications**

For relief of minor skin Irritations due to minor cuts minor scraps insect bites

# Warnings

For external use only avoid contact with eyes

If contact occurs rinse thoroughly with water.

# When using this product stop using and contact a doctor if

condition persists or gets worse symptoms do not improve within 7 days

# Keep out of reach of children.

In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

In case of eye contact flush eyes with running water for 15 minutes.

#### **Directions**

Apply liberally to the afflicted area as often as necessary

# **Inactive ingredients**

Alcohol 14%

#### New label





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witch hazel liquid

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:76772-029

**Route of Administration** TOPICAL

## **Active Ingredient/Active Moiety**

Ingredient Name Basis of Strength Strength

**WITCH HAZEL** (UNII: 101I4J0U34) (WTCH HAZEL - UNII:101I4J0U34) WTCH HAZEL 855 mg in 1 mL

#### **Inactive Ingredients**

Ingredient Name Strength

ALCOHOL (UNII: 3K9958V90M)

WATER (UNII: 059QF0KO0R)

# **Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:76772-029- 95	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/23/2021	

# **Marketing Information**

	101.110.111.9 111.01.11.01.1							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date					
OTC monograph final	part347	06/23/2021						

**Labeler -** TSM ITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI (533120570)

Registrant - TSM ITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI (533120570)

# **Establishment**

Name	Address	ID/FEI	<b>Business Operations</b>			
TSM ITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI		533120570	manufacture(76772-029)			

Revised: 6/2021 TSM ITHALAT IHRACAT SANAYI VE DIS TICARET LIMITED SIRKETI