

BLUTIZER HAND SANITIZER GEL- alcohol solution, gel forming, extended release
CampusORG Turizm Organizasyon Reklamcılık Pazarlama Sanayi ve 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.

Alcohol %70 (%96,4 volume) v/v Purpose: Antiseptic

Purpose

Antiseptic: Hand Sanitizer

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

For external use only. Flammable. Keep away from heat of flame.

Do Not Use

in children less than 2 months of age.

on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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

Place enough product on hands to cover all surfaces. Rub hands together until dry.

Supervise children under 6 years of age when using this product to avoid swallowing.

Store between 15-43C (59-110F)

Avoid freezing and excessive heat above 43C (110F)

- Isopropyl Alcohol %3 (Purpose: Antiseptic and Anti-Foaming)
- Glycerin (Purpose: Humidifier)
- Hydrogen Peroxide (Purpose: Sterilizing)
- Propylene Glycol
- Isopropyl Myristate
- Trolamine
- Carbomer
- Purified Water USP (Purpose: Solvent)

1000 mL (33 fl oz) NDC: 77184-135-11

CAUTION
Highly flammable. Keep away from fire or flame.
For external use only. Avoid eyes. In case of eye contact, flush with water. Discontinue use if skin irritation occurs. If condition persists consult a doctor. Keep out of reach of children.



Blutizer Hand Sanitizer kills 99.9% of germs instantly without water. Use anytime, anywhere: while in car, office, handbag, picnics, nappy change, travel, sports etc. Leaves your hands refreshed. Use as often as required.

RECOMMENDED FORMULA

%70+ Alcohol

1 lt (33 fl oz)



Manufactures: Blutizer Company(OIG) Ltd. 5th. Istanbul TURKEY
Certificated By: ISO, CE, mSDS, Code: 102838
FDA Approval Product Number: 77184-135
www.blutizer.com

Drug Facts:

Active ingredients	Purpose
70%+ Alcohol %70+ Alcohol	Antiseptic
Use	Hand sanitizer to help reduce virus and bacteria on the skin.
Warnings	Flammable. Keep away from the fire or flame.
For external use only.	
When using this product, do not use in or near the eyes. In case of contact, rinse eyes with clean water.	
Stop use and ask a doctor if, irritation or rash appears and lasts.	
Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away.	
DIRECTIONS: Put enough product in your palm to cover hands and rub hands together briskly until dry. Children under 6 years old, should be supervised when using BLUZIZER.	
Other information: Store below 43°C (110°F). May discolor certain fabrics or surfaces.	
Inactive Ingredients: Deionized Water, Isopropyl Alcohol, % 5%, Hydrogen Peroxide, Propylene Glycol, Glycerin, Carbomer, Isopropyl Myristate, Triethanolamin.	
1 lt (33 fl oz)	



BLUTIZER HAND SANITIZER GEL

alcohol solution, gel forming, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77184-135
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.1 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL

ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	0.02 mL in 100 mL
ISOPROPYL ALCOHOL (UNII: ND2M416302)	3 mL in 100 mL
CARBOMER 980 (UNII: 4Q93RCW27E)	0.28 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.28 mL in 100 mL
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77184-135-11	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
2	NDC:77184-135-12	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
3	NDC:77184-135-13	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	
4	NDC:77184-135-14	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
5	NDC:77184-135-15	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
6	NDC:77184-135-16	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
7	NDC:77184-135-17	35 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
8	NDC:77184-135-19	5000 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
9	NDC:77184-135-20	10000 mL in 1 DRUM; Type 0: Not a Combination Product	03/30/2020	
10	NDC:77184-135-21	3 mL in 1 PACKET; Type 0: Not a Combination Product	03/30/2020	
11	NDC:77184-135-22	5 mL in 1 PACKET; Type 0: Not a Combination Product	03/30/2020	
12	NDC:77184-135-23	7 mL in 1 PACKET; Type 0: Not a Combination Product	03/30/2020	
13	NDC:77184-135-24	10 mL in 1 PACKET; Type 0: Not a Combination Product	03/30/2020	
14	NDC:77184-135-34	430 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - CampusORG Turizm Organizasyon Reklamcilik Pazarlama Sanayi ve Ticaret Limited Sirketi (519903395)

Registrant - CampusORG Turizm Organizasyon Reklamcilik Pazarlama Sanayi ve Ticaret Limited Sirketi (519903395)

Establishment

Name	Address	ID/FEI	Business Operations

CampusORG Turizm Organizasyon Reklamcılık Pazarlama Sanayi ve
Ticaret Limited Sirketi

519903395

manufacture(77184-135) , relabel(77184-
135) , label(77184-135)

Revised: 8/2020

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