

KONIX- alcohol solution

Turkuaz Saglik Hizmetleri Medikal Temizlik Kimyasal Urunler Sanayi ve Tic. AS

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.

Antiseptic Hand Rub

This is a hand rub manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Rub Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand rub is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 80% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Rub

Use

Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

Warnings

For external use only. Flammable. Keep away from heat or 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.

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away.

Directions

- 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.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Alcohol Antiseptic 80 %

Topical Solution Antiseptic Hand Rub Non-sterile Solution

5 ml 0.17fl.OZ NDC: 73107-102-40

	<table border="1"><tr><td colspan="2">Drug Facts</td></tr><tr><td>Active ingredient(s) Alcohol 80% v/v.....</td><td>PurposeAntiseptic</td></tr><tr><td colspan="2">Use(s) Health care personnel hand rub to help reduce bacteria that potentially can cause disease.</td></tr><tr><td colspan="2">Warnings For external use only. Flammable. Keep away from heat or flame. Do not use<ul style="list-style-type: none">• in children less than 2 months of age• on open skin wounds</td></tr><tr><td colspan="2">When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.</td></tr><tr><td colspan="2">Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.</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 •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.</td></tr><tr><td colspan="2">Other information •Store between 15-30C (59-86F) •Avoid freezing and excessive heat above 40C (104F)</td></tr><tr><td colspan="2">Inactive ingredients glycerin, hydrogen peroxide, purified water USP</td></tr></table> <p>REF T0000.137.0001 Rev.: 00/25.03.2020 Cod:06.02.1493</p> <p>Manufacturer and License Owner: turkuaz Turkuaz Sağlık Hizmetleri Medikal Temizlik Kimyasal Ürünler San. Ve Tic. A.Ş. Yakuplu Mahallesi Birlik Caddesi No.: 32/1 34524 Beylikdüzü / İstanbul / TÜRKİYE Phone Number: +90 212 428 68 48 Fax: +90 212 428 68 53 www.turkuazsaglik.com.tr info@turkuazsaglik.com.tr</p>	Drug Facts		Active ingredient(s) Alcohol 80% v/v.....	PurposeAntiseptic	Use(s) Health care personnel hand rub to help reduce bacteria that potentially can cause disease.		Warnings For external use only. Flammable. Keep away from heat or flame. Do not use <ul style="list-style-type: none">• 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.		Directions •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.		Other information •Store between 15-30C (59-86F) •Avoid freezing and excessive heat above 40C (104F)		Inactive ingredients glycerin, hydrogen peroxide, purified water USP	
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30 ml 1fl.OZ NDC: 73107-102-30



**Alcohol Antiseptic 80%
Topical Solution**

Antiseptic Hand Rub
Non-sterile Solution

30 mL e 1 fl. OZ.

NDC 73107-102-30

50 ml 1.7fl.OZ NDC: 73107-102-31

Drug Facts	
Active ingredient (s) Alcohol 80% v/v.....	Purpose Antiseptic
Use(s) Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
Warnings For external use only. Flammable. Keep away from heat or flame.	
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REF T0000,137,0001 Rev. 00/25.03.2020 Cod:06.02.1493

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8 681715 344522



**Alcohol Antiseptic 80%
Topical Solution**

Antiseptic Hand Rub
Non-sterile Solution

50 mL e 1.7 fl. OZ.


NDC 73107-102-31

85 ml 2.8fl.OZ NDC: 73107-102-32

Drug Facts	
Active ingredient (s) Alcohol 80% v/v.....	Purpose Antiseptic
Use(s) Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
Warnings For external use only. Flammable. Keep away from heat or flame.	
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REF T0000,137,0001 Rev. 00/25.03.2020 Cod:06.02.1493

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8 681715 344539

KONIX[®]

Alcohol Antiseptic 80%
Topical Solution

Antiseptic Hand Rub
Non-sterile Solution

85 mL e 2.8 fl. OZ.

NDC 73107-102-32

Drug Facts

Active ingredient (s)	Purpose
Alcohol 80% v/v.....	Antiseptic

Use(s) Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

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Inactive ingredients glycerin, hydrogen peroxide, purified water USP

REF: 70000.137.0001 Rev: 00/25.03.2020 Cod:06.02.1483

Manufacturer and License Owner: **turkueaz**
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8 681715 344546

100 ml 3.4fl.OZ NDC: 73107-102-33

KONIX[®]

Alcohol Antiseptic 80%
Topical Solution

Antiseptic Hand Rub

Non-sterile Solution

100 mL e 3.4 fl. OZ.

NDC 73107-102-33

Drug Facts

Active ingredient (s)	Purpose
Alcohol 80% v/v.....	Antiseptic

Use(s) Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

Warnings

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Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Manufacturer and License Owner: **turkuaz**
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REF: T0000.137.0001 Rev.: 00/25.03.2020 Cod:06.02.1493



8 681715 344423

150 ml 5fl.OZ NDC: 73107-102-34

KONIX[®]

Alcohol Antiseptic 80%
Topical Solution

Antiseptic Hand Rub

Non-sterile Solution

150 mL e 5 fl. OZ.

NDC 73107-102-34

Drug Facts

Active ingredient (s)	Purpose
Alcohol 80% v/v.....	Antiseptic

Use(s) Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

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REF | 70000.137.0001 Rev.: 00/25.03.2020 Cod:06.02.1493

turkuaz[®]

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8 681715 344533

200 ml 6.7fl.OZ NDC: 73107-102-35

KONIX[®]

Alcohol Antiseptic 80%
Topical Solution

Antiseptic Hand Rub

Non-sterile Solution

200 mL e 6.7 fl. OZ.

NDC 73107-102-35

Drug Facts

Active ingredient (s)	Purpose
Alcohol 80% v/v.....	Antiseptic

Use(s) Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

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turkuaz

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REF: T0000137.0001 Rev: 00/25.03.2020 Cod:06.02.1493



8 681715 344560

250 ml 8.5fl.OZ NDC: 73107-102-36

KONIX[®]

Alcohol Antiseptic 80%
Topical Solution

Antiseptic Hand Rub

Non-sterile Solution

250 mL e 8.5 fl. OZ.

NDC 73107-102-36

Drug Facts

Active ingredient (s)	Purpose
Alcohol 80% v/v.....	Antiseptic

Use(s) Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

Warnings

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Other information •Store between 15-30C (59-86F)
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Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Manufacturer and License Owner: **turkuaz**
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REF | T0000137.0001 Rev.: 00/25.03.2020 Cod:06.02.1493



8 681715 344577

500 ml 16.9fl.OZ NDC: 73107-102-37

KONIX[®]

Alcohol Antiseptic 80%
Topical Solution

Antiseptic Hand Rub

Non-sterile Solution

500 mL e 16.9 fl. OZ.

NDC 73107-102-37

Drug Facts

Active ingredient (s)	Purpose
Alcohol 80% v/v.....	Antiseptic

Use(s) Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

Warnings

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Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Manufacturer and License Owner: **turkuaz**
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REF: T0000137.0001 Rev: 00/25.03.2020 Cod:06.02.1493



8 681715 344584

1000 ml 33.8fl.OZ NDC: 73107-102-36

KONIX[®]

Alcohol Antiseptic 80%
Topical Solution

Antiseptic Hand Rub

Non-sterile Solution

1000 mL e 33.8 fl. OZ.

NDC 73107-102-38

Drug Facts

Active ingredient (s)	Purpose
Alcohol 80% v/v.....	Antiseptic

Use(s) Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

Warnings

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

Do not use

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Other information •Store between 15-30C (59-86F)
•Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Manufacturer and License Owner: **turkuaz**
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REF: T0000137.0001 Rev.: 00/25.03.2020 Cod:06.02.1493



8 681715 344591

5000 ml 169fl.OZ NDC: 73107-102-39

KONIX®

Alcohol Antiseptic 80%
Topical Solution

Antiseptic Hand Rub
Non-sterile Solution

5000 mL e 169 fl. OZ.

NDC 73107-102-39

Drug Facts

Active ingredient (s)	Purpose
Alcohol 80% v/v.....	Antiseptic

Use(s) Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

Warnings

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Inactive ingredients glycerin, hydrogen peroxide, purified water USP

Manufacturer and License Owner: **turkuaz**
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REF: T0000.137.0001 Rev.: 00/25.03.2020 Cod:06.02.1493



8 681715 344607

KONIX

alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73107-102
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	18.425 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73107-102-33	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/07/2020	
2	NDC:73107-102-34	150 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/07/2020	
3	NDC:73107-102-35	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/07/2020	
4	NDC:73107-102-36	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/07/2020	
5	NDC:73107-102-37	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/07/2020	
6	NDC:73107-102-38	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/07/2020	
7	NDC:73107-102-39	5000 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/07/2020	
8	NDC:73107-102-32	85 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/07/2020	
9	NDC:73107-102-31	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/07/2020	
10	NDC:73107-102-30	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/07/2020	
11	NDC:73107-102-40	5 mL in 1 PACKET; Type 0: Not a Combination Product	04/07/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/07/2020	

Labeler - Turkuaz Saglik Hizmetleri Medikal Temizlik Kimyasal Urunler Sanayi ve Tic. AS (356325295)

Establishment

Name	Address	ID/FEI	Business Operations
Turkuaz Saglik Hizmetleri Medikal Temizlik Kimyasal Urunler Sanayi ve Tic. AS		356325295	manufacture(73107-102)

Revised: 4/2020

Turkuaz Saglik Hizmetleri Medikal Temizlik Kimyasal Urunler Sanayi ve Tic. AS