ANTISEPTIC LIQUID- benzalkonium chloride soap
ITIMAT KOZMETIK URUNLERI SANAYI VE TICARET ANONIM 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.

FONEX ANTISEPTIC LIQUID SOAP

Drug Facts

Active ingredient

0,5% (w/w) Benzalkonium Chloride

Purpose

Antiseptic

Uses

• hand sanitizer to decrease bacteria on the skin
• recommended for repeated use

Warnings

For external use only

Do not use

• in children less than 2 months of age
• on open skin wounds

When using this product • do not get into eyes. In case of contact, rinse eyes thoroughly with water
Stop use and ask a doctor if
• irritation and redness develop
• condition persists for more than 72 hours

Keep out of reach of children.

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

Directions

• Squeeze a few pumps into your palms, foam with water and rinse.
• supervise children under 6 years of age when using this product to avoid swallowing

Other information

• store between 15-30°C (59-86°F)
• avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients

Deionised Water, Cocamidopropyl Betaine, Sodium Cocoamphoacetate, Lauryl Glucoside, Glycerin,

PEG-150 Distearate, Hydrogenated Castor Oil,
Sodium Chloride, Citric Acid, CI 42090

Questions?

+1-646-301-0044
You may also report serious side effects to this phone number.

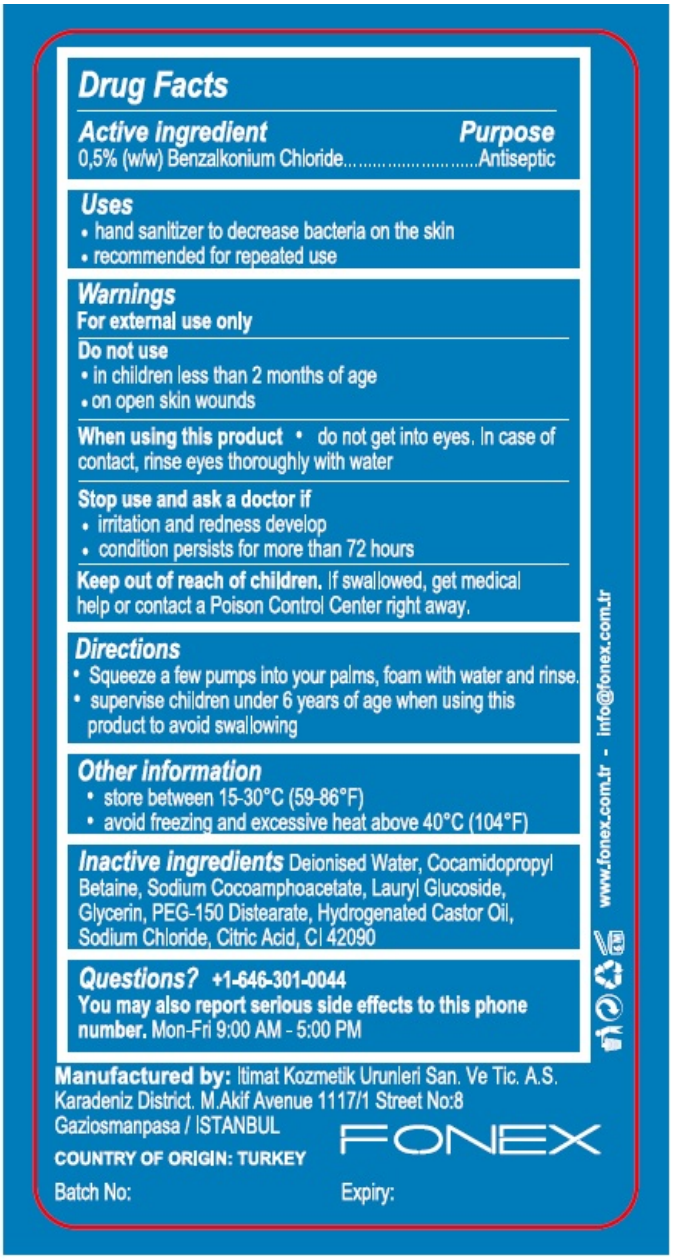
Mon-Fri 9:00 AM - 5:00 PM

Manufactured by: Itimat Kozmetik Urunleri San. Ve Tic. A.S.
Karadeniz District. M.Akif Avenue 1117/1 Street No:8
Gaziosmanpasa / ISTANBUL
COUNTRY OF ORIGIN: TURKEY
Batch No:

Expiry:

www.fonex.com.tr - info@fonex.com.tr

Packaging



ANTISEPTIC LIQUID

benzalkonium chloride soap

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:79392-102
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SODIUM COCOAMPHOACETATE (UNII: W7Q5E87674)	
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79392-102-01	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/20/2020	
2	NDC:79392-102-02	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/20/2020	
3	NDC:79392-102-03	150 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/20/2020	
4	NDC:79392-102-04	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/20/2020	
5	NDC:79392-102-05	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/20/2020	
6	NDC:79392-102-06	750 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/20/2020	
7	NDC:79392-102-07	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/20/2020	
8	NDC:79392-102-08	1500 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/20/2020	
9	NDC:79392-102-09	2000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/20/2020	
10	NDC:79392-102-10	2500 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/20/2020	
11	NDC:79392-102-11	3000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/20/2020	
12	NDC:79392-102-12	3500 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/20/2020	
13	NDC:79392-102-13	4000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/20/2020	
14	NDC:79392-102-14	4500 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/20/2020	
15	NDC:79392-102-15	5000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/20/2020	
16	NDC:79392-102-16	10000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/20/2020	
17	NDC:79392-102-17	20000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/20/2020	
18	NDC:79392-102-18	36 in 1 BOX	07/20/2020	
18		50 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph not final	part333E	07/20/2020	

Labeler - ITIMAT KOZMETIK URUNLERI SANAYI VE TICARET ANONIM SIRKETI (356579552)

Establishment

Name	Address	ID/FEI	Business Operations
ITIMAT KOZMETIK URUNLERI SANAYI VE TICARET ANONIM SIRKETI		356579552	manufacture(79392-102)

Revised: 7/2020 ITIMAT KOZMETIK URUNLERI SANAYI VE TICARET ANONIM SIRKETI