

BIONAMICS- ethyl alcohol spray
ALA MEDICAL GROUP PTY 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.

BIONAMICS

Active Ingredient

Ethyl Alcohol

Purpose

Antiseptic

Uses

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

Warnings

For external use only. Flammable.
Keep away from fire and flame.

Do not use - in children less than 2 months of age.
- on open skin wounds.

When using this product Avoid contact with eyes. In case of eye contact, rinse with water immediately.

Stop use and ask a doctor if irritation and rash appears and lasts.

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

Directions

- Place enough product in your palm to spread on both hands.
- Rub your hands together thoroughly until dry.
- Children under 6 years of age should be supervised by an adult when using this product to avoid swallowing.

Inactive ingredients

Water, Glycerin, Tocopherol Acetate.

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Centre immediately.

Products Labels



HAND SANITISER

SPRAY



QUALITY PRODUCT


50ml / 1.69fl.oz

Drug Facts	
Active ingredients[s] Ethyl Alcohol 75% v/v	Purpose Antiseptic
Use[s] Hand sanitiser to help reduce bacteria that potentially can cause disease. For use when soap and water are not available. Recommended for repeated use.	
Warnings For external use only. Flammable. Keep away from fire and flame.	
Do not use - in children less than 2 months of age. - on open skin wounds.	
When using this product Avoid contact with eyes. In case of eye contact, rinse with water immediately.	
Stop use and ask a doctor if irritation and rash appears and lasts.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Centre immediately.	
Directions Place enough product in your palm to spread on both hands. Rub your hands together thoroughly until dry. Children under 6 years of age should be supervised by an adult 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 Water, Glycerin, Tocopherol Acetate	

MFG MM/YYYY
EXP MM/YYYY
#####

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HAND SANITISER

SPRAY



QUALITY PRODUCT


100ml / 3.38fl.oz

Drug Facts	
Active ingredients[s] Ethyl Alcohol 75% v/v	Purpose Antiseptic
Use[s] Hand sanitiser to help reduce bacteria that potentially can cause disease. For use when soap and water are not available. Recommended for repeated use.	
Warnings For external use only. Flammable. Keep away from fire and flame.	
Do not use - in children less than 2 months of age - on open skin wounds	
When using this product Avoid contact with eyes. In case of eye contact, rinse with water immediately.	
Stop use and ask a doctor if irritation and rash appears and lasts	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Centre immediately.	
Directions - Place enough product in your palm to spread on both hands. Rub your hands together thoroughly until dry. - Children under 6 years of age should be supervised by an adult 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 Water, Glycerin, Tocopherol Acetate	

MFG MM/YYYY
EXP MM/YYYY
#####

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HAND SANITISER

SPRAY



QUALITY PRODUCT



250ml / 8.45fl.oz

MFG MM/YYYY
EXP MM/YYYY
#####

Drug Facts

Active ingredients[s]	Purpose
Ethyl Alcohol 75% v/v	Antiseptic

Use[s]

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

Warnings For external use only. Flammable. Keep away from fire and flame.

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- on open skin wounds

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Inactive ingredients Water, Glycerin, Tocopherol Acetate

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HAND SANITISER



QUALITY PRODUCT



500ml / 16.9fl.oz

MFG MM/YYYY
EXP MM/YYYY
#####

Drug Facts

Active ingredients[s]	Purpose
Ethyl Alcohol 75% v/v	Antiseptic

Use[s] Hand sanitiser to help reduce bacteria that potentially can cause disease. For use when soap and water are not available. Recommended for repeated use.

Warnings For external use only. Flammable. Keep away from fire and flame.

Do not use - in children less than 2 months of age
- on open skin wounds

When using this product Avoid contact with eyes. In case of eye contact, rinse with water immediately.

Stop use and ask a doctor if irritation and rash appears and lasts

Drug Facts (cont.)

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Centre immediately.

Directions

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- Children under 6 years of age should be supervised by an adult when using this product to avoid swallowing.

Other information

- Store between 15-30C (59-86F)
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Inactive ingredients Water, Glycerin, Tocopherol Acetate

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BIONAMICS

ethyl alcohol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74198-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74198-002-01	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/28/2020	
2	NDC:74198-002-02	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/28/2020	
3	NDC:74198-002-03	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/28/2020	
4	NDC:74198-002-04	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/28/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/28/2020	

Labeler - ALA MEDICAL GROUP PTY LTD (746915311)**Establishment**

Name	Address	ID/FEI	Business Operations
Henan Bangruite Industry Co., Ltd		525663153	manufacture(74198-002)

Revised: 3/2020

ALA MEDICAL GROUP PTY LTD