ZIVA WATER WIPES- benzalkonium chloride cloth Ziva Wetwipes FZCo

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.

Drug Facts

Active Ingredient:

Benzalkonium Chloride 0.01%

Direction for use

For external use only. Open the flip top & peel back the front label slowly. Pull one wipe at a time. Gently cleanse your baby's skin using one or more wipes. Reseal pouch by firmly running thumb over label and close the flip top to prevent moisture loss.

Precautions:

Do not apply to irritated or damaged skin. In case of gluteal erythema (redness of skin), contact your doctor or pharmacist. Keep in a cool place away from direct sunlight. Prevent contact with eyes. In case of irritation wash away with water immediately.

Other information

Store below 25°C

Ingredients

Aqua, Pyrus Malus (apple) fruit extract, Benzalkonium Chloride.

Product label

Ingredients: Aqua, Pyrus malus (apple) fruit extract, Benzalkonium chloride water wipes Direction for use: Open the flip top & peel back the front label slowly. Pull one wipe at a time. Gently cleanse your baby's skin using one or more wipes. Reseal pouch by firmly running thumb over label and close the flip top to prevent moisture loss. Precautions: Do not apply to irritated or damaged skin. In case of gluteal erythema (redness of skin), contact your doctor or pharmacist. Keep in a cool place away from direct sunlight. Prevent contact with eyes. In case of irritation wash away with water immediately. 31VM %6. 99.9% Water with a drop of truit extract Soap Free Formula, Delicate For Baby's Skin water wipes 99.9% Water with a drop of fruit extract No Perfume WATER WIPES No Alcohol No Paraben Active Ingredient: Benzalkonium Chloride 0.01% 100 wipes



benzalkonium chloride cloth

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:81450-006

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM -	BENZALKONIUM	0.01 g

UNII:7N6JUD5X6Y)

CHLORIDE

0.01 g in 100 mL

Inactive Ingredients

g. canonia			
Ingredient Name	Strength		
APPLE FRUIT OIL (UNII: 9NT987I3A8)			
WATER (LINIUS OF OF OKOOD)			

WATER (UNII: 059QF0KO0R)

Packaging

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	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:81450- 006-01	100 in 1 PACKAGE	12/24/2021	
	1	6.12 mL in 1 NOT APPLICABLE; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC monograph not final	part333A	12/24/2021	

Labeler - Ziva Wetwipes FZCo (559186188)

Registrant - Dirra USA (117678868)

Establishment			
Name	Address	ID/FEI	Business Operations
Ziva Wetwipes FZCO		559186188	manufacture(81450-006)

Revised: 12/2021 Ziva Wetwipes FZCo