

ZIVA BABY WIPES- zinc oxide cloth
Ziva Wetwipes FZCo

Drug Facts

Active Ingredient:

Zinc Oxide 0.1%

Direction for use

Peel back the front label or open the flip top slowly. Pull wipes as needed. Gently cleanse your baby's skin using one or more wipes. Reseal pouch by firmly running thumb over label to close the flip top to prevent moisture loss.

Precautions:

For external use only. 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.

Keep out of reach of children

Store below 25°C

Ingredients:

Aqua, Zinc Oxide, Pentylene Glycol and Glyceryl Caprylate / Caprate, Aloe Barbadensis Leaf Juice, Tocopheryl Acetate (Vitamin E), Propylene Glycol, Sodium cocoamphoacetate, Disodium cocoamphodiacetate, Cocamidopropyl Betaine, PEG 40 Hydrogenated Castor Oil, Chamomile Extract, PEG-120 Methyl Glucose Dioleate, Disodium EDTA, Citric Acid.

Product label

ZIVA BABY WIPES			
zinc oxide cloth			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81450-005
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)		ZINC CATION	0.1 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
WATER (UNII: 059QF0KO0R)	
GLYCERYL CAPRYLATE/CAPRATE (UNII: G7515SW10N)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
CHAMOMILE (UNII: FGL3685T2X)	
SODIUM COCOAMPHOACETATE (UNII: W7Q5E87674)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DISODIUM COCOAMPHODIACETATE (UNII: 18L9G3U51M)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
METHYL GLUCOSE DIOLEATE (UNII: FA9KFJ4Z6P)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81450-005-01	80 in 1 PACKAGE	12/24/2021	
1		4.59 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M003	12/24/2021	

Labeler - Ziva Wetwipes FZCo (559186188)**Registrant** - Dirra USA (117678868)**Establishment**

Name	Address	ID/FEI	Business Operations
Ziva Wetwipes FZCO		559186188	manufacture(81450-005)

Revised: 10/2023

Ziva Wetwipes
FZCo