SMILE ANTIBACTERIAL WET WIPES PLANTAIN EXTRACT- benzalkonium chloride cloth KPD, Limited Liability Company

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.

Smile Antibacterial Wet Wipes Plantain Extract

Drug Facts

Active Ingredient

Benzalkonium Chloride 0,1%

Purpose

Antibacterial

Uses

kill germs and remove dirt

Warnings

For external use only

Don't use

if you are alleric to any of the any of ingredients

When using this product

do not get into eyes. If contact occurs, wash thoroughly with water

Stop use and ask doctor

if irritation or rash develops and continuous for more than 72 hours

Keep out of reach of children

Directions

- Adults and children 3 years and over
- Children under 3 years ask a doctor before use
- Wipe with wipes and let dry

Inactive ingredients:

aqua, glycerin, propylene glycol, plangato major leaf extract, PEG-40 hydrogenated castro oil, cocamidopropyl betaine, PPG-2-methyl ether, ethylparaben, 2-bromo-2-nitropropane-1,3-doil, centrimonium bromide, citric acid, parfum, linalool, butylphenyl methylpropional

Package Labeling:



SMILE ANTIBACTERIAL WET WIPES PLANTAIN EXTRACT

benzalkonium chloride cloth

Product Information	uct Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81119-001	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1 mg in 1 mL	

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
GLYCERIN (UNII: PDC6 A3C0 OX)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
PLANTAGO MAJOR LEAF (UNII: 7DC28 K241X)		
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)		
COCAMIDO PRO PYL BETAINE (UNII: 50CF3011KX)		
PPG-2 METHYL ETHER (UNII: RQ1X8FMQ9N)		

ETHYLPARABEN (UNII: 14255EXE39)		
BRONOPOL (UNII: 6PU1E16C9W)		
CETRIMO NIUM BRO MIDE (UNII: L64N7M9BWR)		
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)		
LINALOOL, (+/-)- (UNII: D8 1Q Y6 I8 8 E)		
CITRAL (UNII: T7EU0O9VPP)		

ı	P	Packaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:81119 - 001-15	15 in 1 PACKAGE	05/01/2020	
	1		2.28 mL in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/01/2020	

Labeler - KPD, Limited Liability Company (681241494)

Revised: 12/2020 KPD, Limited Liability Company