BABY- talc powder
Walgreen 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.

BABY POWDER

Active ingredient

Talc 100%

Purpose

Skin Protectant

Uses
Keeps skin soft, fresh & comfortable.

Warnings

For external use only.

Keep out of reach of children

Close tightly after use.

Do not use on broken skin.

Avoid contact with eyes.

Keep powder away from child’s face to avoid inhalation, which can cause breathing problems.

Directions

Shake powder into your hand and smooth onto skin.

Storage

Store in a cool, dry place.

Inactive ingredient

Fragrance

Package/Label Principal Display Panel

Baby Powder

Keeps skin soft, fresh & comfortable

Clinically Tested

NET WT 4 OZ (113 g)

BABY

talc powder

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0363-0901
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TALC (UNII: 7SEV7J4R1U) (TALC - UNII:7SEV7J4R1U)	TALC	100 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
FRAGRANCE CLEAN ORC0600327 (UNII: 329LCV5BTF)	0.1 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0901-04	113 g in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2020	
2	NDC:0363-0901-15	425 g in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2020	
3	NDC:0363-0901-22	623 g in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part347	07/17/2014	

Labeler - Walgreen Company (008965063)

Registrant - Jell Pharmaceuticals Pvt. Ltd. (726025211)

Establishment

Name	Address	ID/FEI	Business Operations
Jell Pharmaceuticals Pvt. Ltd.		726025211	manufacture(0363-0901)

Revised: 8/2020 Walgreen Company