# MEDICATED CORNSTARCH BABY POWDER- active corn starch powder Davion, Inc.

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.

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#### **Medicated Cornstarch Baby Powder**

#### **Active Ingredients**

Corn Starch 79%

Kaolin 4%

Zinc Oxide 15%

#### **Purposes**

Skin Protectant

#### Uses

- Prevents chafed skin and reduces minor skin irritations due to diaper rash
- Helps protect from wetness

#### Warnings

For external use only.

#### When using this product

- Avoid contact with eyes
- Do not use on broken skin
- Keep powder away from child's face to avoid inhalation which can cause breathing problems

#### Stop use and ask a doctor if

• If conditions worsen or symptoms do not get better within 7 days

#### Keep out of reach of children.

If ingested, get medical help or contact a Poison Control Center immediately.

#### Directions

**Babies:** Change wet and soiled diaper promptly, cleanse the diaper area and allow to dry. Apply powder liberally as often as necessary, with each diaper change, especially at bedtime, or anytime when exposure to wet diapers may be prolonged. Apply powder close to the body away from child's face. Carefully shake the powder into the diaper or into the hand and apply to diaper area.

**Adults and children 2 years and older:** apply freely up to 3 or 4 times daily. For best results, dry skin thoroughly before applying.

#### **Inactive ingredients**

Fragrance, Silica



### Drug Facts Active ingredients **Purposes** Cornstarch 79% ..... Skin Protectant Kaolin 4% .....Skin Protectant Zinc Oxide 15% .....Skin Protectant Uses Prevents chafed skin and reduces minor skin irritations due to diaper rash Helps protect from wetness For external use only When using this product Avoid contact with eyes ■ Do not use on broken skin ■ Keep powder away from child's face to avoid inhalation which can cause breathing problems. Stop use and ask a doctor if conditions worsen or symptoms do not get better within 7 days Keep out of reach of children. If ingested, get medical help or contact a Poison Control Center right away. Directions: Babies - Change wet and soiled diapers promptly, cleanse the diaper area and allow to dry. Apply powder liberally as often as necessary, with each diaper change, especially at bedtime, or anytime when exposure to wet diapers may be prolonged. Apply powder close to the body away from child's face. Carefully shake the powder into the diaper area. Adults and children 2 yrs and older: Apply freely up to 3 or 4 times daily. For best results, dry skin thoroughly before applying. Inactive ingredients: Fragrance, This product is sold by weight, not by volume. This product is sold by weight, not by volume. Some setting will occur, \*This product is not manufactured or distributed by Chattern, Inc., distributor of Gold Bond® Cornstarch Plus Baby Powder. Distributed by: CVS Pharmacy, Inc. One CVS Drive, Woonsocket, RI 02895 © 2016 CVS/pharmacy Made in USA V-10889

#### MEDICATED CORNSTARCH BABY POWDER

active corn starch powder

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42669-231
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
STARCH, CORN (UNII: O8232NY3SJ) (STARCH, CORN - UNII:O8232NY3SJ)	STARCH, CORN	89.27 g in 113 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	16.95 g in 113 g
KAOLIN (UNII: 24H4NWX5CO) (KAOLIN - UNII:24H4NWX5CO)	KAOLIN	4.52 g in 113 g

Inactive Ingredients	
Ingredient Name	Strength
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	

	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date

1 NDC:42669-231-04	113 g in 1 BOX; Type 0: Not a Combination Product	09/01/2016		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part347	09/01/2016		

## **Labeler -** Davion, Inc. (174542928)

Registrant - Davion, Inc. (174542928)

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