

CALDESENE BABY- starch, corn and zinc oxide powder
Insight Pharmaceuticals LLC

Caldesene Baby Powder 636736-305

Caldesene®
Baby

Drug Facts

Active ingredients

Cornstarch 81%

Zinc Oxide 15%

Purpose

Skin Protectant

Skin Protectant

Uses

- helps treats and prevents diaper rash
- temporarily protects and helps relieve minor skin irritation

Warnings

For external use only.

Do not use

on broken skin.

When using this product

- do not get into eyes
- keep away from child's face and mouth to avoid breathing it

Stop use and ask a doctor if

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

For diaper rash

- change wet or 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 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

For minor skin irritations

- smooth on powder to protect irritated and chafed skin. Apply as needed.

Other information

- Store at room temperature 15°-25°C (59°-77°F).
- See container bottom for lot number and expiration date.

Inactive ingredients

aloe vera gel, chamomile, fragrance, kaolin, tricalcium phosphate

Questions?

1-800-344-7239 or visit our website at **www.caldesene.com**

PRINCIPAL DISPLAY PANEL - 142 g Label

Caldesene®

Baby

*Skin Protectant / Cornstarch Powder 18%
and Zinc Oxide 15%*

NET WT 5 OZ (142 g)

TREATS & PROTECTS



SKIN PROTECTANT / CORNSTARCH 81%
AND ZINC OXIDE 15%

PROTECTING POWDER



- Plus Skin-Soothing Aloe and Chamomile
- Helps Treat & Prevent Diaper Rash
- Helps Protect Against Irritated/Chafed Skin

NET WT.
5 OZ (142 g)

FREE FROM

TALC
DYES PARABENS
PRESERVATIVES

Caldesene[®] Baby

Contains Cornstarch and Zinc Oxide which form a protective barrier to repel moisture and help keep skin dry, plus Aloe and Chamomile. When used regularly, Caldesene soothes and softens your baby's delicate skin and seals out wetness to help protect against chafed skin.

Drug Facts		Drug Facts (continued)
Active ingredients	Purpose	Directions
Cornstarch 81% Zinc Oxide 15%	Skin Protectant Skin Protectant	For diaper rash <ul style="list-style-type: none"> • change wet or 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 any time 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
Uses	<ul style="list-style-type: none"> • helps treat and prevent diaper rash • temporarily protects and helps relieve minor skin irritation 	For minor skin irritations <ul style="list-style-type: none"> • smooth on powder to protect irritated and chafed skin. Apply as needed.
Warnings	<p style="font-size: x-small;">For external use only.</p> <p style="font-size: x-small;">Do not use on broken skin.</p> <p style="font-size: x-small;">When using this product</p> <ul style="list-style-type: none"> • do not get into eyes • keep away from child's face and mouth to avoid breathing it <p style="font-size: x-small;">Stop use and ask a doctor if</p> <ul style="list-style-type: none"> • condition worsens • symptoms last more than 7 days or clear up and occur again within a few days <p style="font-size: x-small;">Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.</p>	Other information <ul style="list-style-type: none"> • Store at room temperature 15-25°C (59-77°F) • See container bottom for lot number and expiration date.
		Inactive ingredients also vera gel, chamomile, fragrance, kaolin, tricalcium phosphate
		Questions call 1-800-344-7239 or visit our website at www.caldesene.com

Dist. by Insight Pharmaceuticals LLC
Tarrytown, NY 10591
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Made in USA
Product packaged by weight not volume.
CLUS002501



CALDESENE BABY

starch, corn and zinc oxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63736-305
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
STARCH, CORN (UNII: O8232NY3SJ) (STARCH, CORN - UNII:O8232NY3SJ)	STARCH, CORN	115 g in 142 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	21 g in 142 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CHAMOMILE (UNII: FGL3685T2X)	
KAOLIN (UNII: 24H4NWX5CO)	
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	

Contains**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63736-305-05	142 g in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	07/07/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M016	07/07/2009	

Labeler - Insight Pharmaceuticals LLC (055665422)

Revised: 1/2024

Insight Pharmaceuticals LLC