

MEMBERS MARK DIAPER RASH- zinc oxide cream
Sams West 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.

Drug Facts

Active ingredient

Zinc Oxide 13%

Purpose

Skin protectant

Uses

- helps treat and prevent diaper rash
- protects chafed skin due to diaper rash
- helps seal out wetness

Warnings

For external use only.

When using this product

do not get into eyes.

Stop using this product and ask a doctor if

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

Do not use on

- deep puncture wounds
- animal bites
- serious burns

Keep out of reach of children.

In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.

Directions

- change wet and soiled diapers promptly
- clean the diaper area and allow to dry
- apply ointment liberally as often as required with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged.

Other information

store between 20°C - 25°C (68°F - 77°F)

Inactive ingredients

Water (Aqua), Mineral Oil, Petrolatum, Beeswax, Dimethicone, Sorbitan Sesquioleate, Microcrystalline Wax, PEG-30 Dipolyhydroxystearate, Aloe Barbadensis Leaf Juice, Tropolone, Tocopheryl Acetate, 1,2-Hexanediol, Caprylyl Glycol, Magnesium Sulfate, Potassium Hydroxide.

Questions or comments?

1-888-301-0332

Label Copy



zinc oxide
**diaper rash
cream**

RAPID RELIEF

Member's Mark Diaper Rash Cream soothes baby's soft skin, providing gentle relief against diaper rash and a nourishing barrier to shield and protect. Enriched with zinc oxide and provitamin B5 for effective, non-sticky, tender loving care.



zinc oxide
**diaper rash
cream**

RAPID RELIEF

PARABEN & FRAGRANCE FREE

NET WT 6 OZ (170 g)

Drug Facts	Drug Facts (continued)
Active ingredient Purpose Zinc Oxide 13%.....Skin protectant	Keep out of reach of children. In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.
Uses <ul style="list-style-type: none"> helps treat and prevent diaper rash protects chafed skin due to diaper rash helps seal out wetness 	Directions <ul style="list-style-type: none"> change wet and soiled diapers promptly clean the diaper area and allow to dry apply ointment liberally as often as required with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged.
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Stop using this product and ask a doctor if <ul style="list-style-type: none"> condition worsens symptoms last more than 7 days or clear up and occur again within a few days 	Questions or Comments? 1-888-301-0332
Do not use on <ul style="list-style-type: none"> deep puncture wounds animal bites serious burns 	

DISTRIBUTED BY SAM'S WEST, INC.
BENTONVILLE, AR 72716
MADE IN CANADA

12-13484

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68196-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	13 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
TROPOLONE (UNII: 7L6DL16P1T)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68196-002-06	170 g in 1 TUBE; Type 0: Not a Combination Product	08/07/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/07/2017	

Labeler - Sams West Inc (051957769)

Registrant - Apollo Health and Beauty Care Inc. (201901209)

Establishment

Name	Address	ID/FEI	Business Operations
Apollo Health and Beauty Care Inc.		201901209	manufacture(68196-002)

Revised: 8/2017

Sams West Inc