

BABYSPA SHEA BUTTER DIAPER- zinc oxide cream
EXPRO3 LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).

Drug Facts

Active Ingredients	Purpose
Zinc Oxide 12%.....	Skin Protectant

Uses:

- * Helps treat and prevent diaper rash and other minor skin irritations
- * Seals out wetness

Keep out of reach of children

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

Directions:

Apply cream liberally, as often as necessary, with each diaper change for continuous protection

Warnings:

For external use only

Stop use and ask a doctor if:

- * condition worsens
- * symptoms last more than 7 days

shea butter (butyrospermum parkii), aloe barbadensis gel, cocoa (theobroma cacao) butter, beeswax, potato (solanum tuberosum) starch, cetearyl alcohol, grape (vitis vinifera) seed oil, kaolin, sesame (sesamum indicum) oil, titanium dioxide, phenoxyethanol, licorice (glycyrrhiza glabra) root extract, calendula officinalis seed oil, Unisooth EG-28 (water propyl gallate gallyl glucoside epigallocatechin gallatyl glucoside), glyceryl caprylate, olive (olea europaea) oil*, glycerin, chamomile (anthemis nobilis) extract, benzoic acid, dehydroacetic acid, borage (borago officinalis) seed oil, evening primrose (oenothera biennis) oil, fragrance, lavender (lavandula angustifolia) extract.

BabySpa.
pampered by nature



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pampered by nature

Shea Butter Diaper Cream

Fresh Baby Scent

Prevents and Treats Diaper Rash with Over 30% Shea Butter

Specially Formulated to Nurture with Aloe, Calendula, Shea Butter & Patented Swiss Moisturizers

12% Zinc Oxide

Newborn **STAGE 1** Crawler

99.3% Natural

3.4 Fl oz (100 ml)

Inspired by ancient traditions and nurturing spa cultures, our **STAGE ONE** Shea Butter Diaper Cream is formulated with over 30% Shea Butter and 12% Zinc Oxide to create a natural barrier against wetness that protects your baby's bottom from diaper rashes. Patented Swiss bioactive moisturizers will effectively treat redness and irritation to provide an instant soothing relief. Our blend of vitamin-rich emollients and botanicals such as Organic Aloe, Calendula, and Coconut Butter helps to reduce soreness and discomfort by restoring the health of your baby's skin. BabySpa Shea Butter Diaper Cream is completely free of toxic substances and comes in a light, non-greasy formula that wipes away clean with just one swipe.

Our collection is specially formulated to best suit your child's environment and unique skin care needs. From newborn to active preschooler, choose the stage that best applies and enjoy our natural and pampering benefits.



Age: ideal for use on newborns through crawlers.



Phthalate FREE
Paraben FREE
Sulfate (SLS) FREE
Polyethylene Glycol (PEG) FREE
Mineral Oil FREE
Bisphenol A (BPA) FREE

Made exclusively for BabySpa® USA
Distributed by: **EXPROS**
New York, NY 10018

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Shea Butter Diaper Cream

Fresh Baby Scent

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Specially Formulated to Nurture with Aloe, Calendula, Shea Butter & Patented Swiss Moisturizers

12% Zinc Oxide

Newborn **STAGE 1** Crawler

99.3% Natural

3.4 Fl oz (100 ml)

Drug Facts

Active Ingredient	Purpose
Zinc Oxide 12%	Skin Protectant

Uses:
• Helps treat and prevent diaper rash and other minor skin irritations
• Soaks out wetness

Warnings:
For external use only

When using this product:
• do not get into eyes

Stop use and ask a doctor if:
• condition worsens
• symptoms last more than 7 days

Keep out of the reach of children
If swallowed, get medical help or contact a Poison Control Center right away (U.S. - 1-800-222-1222)

Directions:
Apply cream liberally, as often as necessary, with each diaper change for continuous protection

Inactive Ingredients:
SHEA BUTTER (BUTYROSPERMIUM PARIETI), ALOE BARBADENSIS GEL*, COCOA (THEOBROMA CACAO) BUTTER, CERA ALBA, POTATO (SOLANUM TUBEROSUM) STARCH, CETEARYL ALCOHOL, GRIFFE (MITSUNERISSEED) OIL, KAOLIN, SESAME (SESAMUM INDICUM) OIL, TITANIUM DIOXIDE, PENTOXETRIANOL, LUDRICE (SCHIMMERIA OLIVARUM) EXTRACT, CALENDULA OFFICINALIS SEED OIL, WAXES & PROPOLIS, GALLATE & BALLYL GLUCOSIDE, EPYRALLOIC ACID, GALLIC ACID, GLYCERIN, CAPRYLATE, OLIVE (OLEA EUROPAEA) OIL, GLYCERIN, CHAMOMILE (ANTHEMIS NOBILIS) EXTRACT*, BENZOIC ACID, DEHYDROACETIC ACID, BORNEBORNAGE OFFICINALIS SEED OIL, EVENING PRIMROSE (GENOTIENA BIENERT) OIL, FRAGRANCE, LAVENDER (LAVANDULA ANGSTREIFOLIA) EXTRACT
*Certified Organic



Made in Israel

BABYSPA SHEA BUTTER DIAPER

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42957-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	120 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SHEA BUTTER (UNII: K49155WL9Y)	
ALOE VERA FLOWER (UNII: 575DY8C1ER)	
COCOA BUTTER (UNII: 512OYT1CRR)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
STARCH, POTATO (UNII: 8I089SAH3T)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
KAOLIN (UNII: 24H4NWX5CO)	
SESAME OIL (UNII: QX10HYY4QV)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
CALENDULA OFFICINALIS SEED OIL (UNII: 9JS8DS42SV)	
WATER (UNII: 059QF0KO0R)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
LAURYL GLUCOSIDE (UNII: 76LN7P7UCU)	
EPIGALLOCATECHIN GALLATE (UNII: BQM438CTEL)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
GLYCERIN (UNII: PDC6A3C0OX)	
CHAMAEMELUM NOBILE FLOWER (UNII: O2T154T6OG)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
DEHYDROACETIC ACID (UNII: 2KAG279R6R)	
BORAGE OIL (UNII: F8XAG1755S)	
OENOTHERA BIENNIS (UNII: 76UI55V071)	
LAVANDULA ANGUSTIFOLIA FLOWER (UNII: 19AH1RAF4M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42957-001-01	100 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		07/18/2012	

Labeler - EXPRO3 LLC (014904067)

Registrant - E.L. Erman Cosmetic Manufacturing Ltd (531894152)

Establishment

Name	Address	ID/FEI	Business Operations
E.L. Erman Cosmetic Manufacturing Ltd		531894152	manufacture(42957-001)

Revised: 7/2012

EXPRO3 LLC