

BABYSPA CALMING RELIEF ECZEMA- colloidal oatmeal cream

Expro3, LLC

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.

☐Active Ingredient ☐Purpose

Colloidal Oatmeal 0.1%.....Skin Protectant

Intensively Hydrates & Naturally Helps to Relieve Dry, Itchy, Irritated Skin due to Eczema & Rashes

Keep out of the reach of children

☐Uses:☐

Temporarily protects and helps relieve minor skin irritation and itching due to:

- eczema
- rashes

☐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 or clear up and occur again within a few days

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

☐Directions:

- Apply liberally to dry, itchy patches and irritated skin, as often as necessary.
- Suitable for daily use.
- Delicate enough to use on newborn skin.

☐Other Information:

For use on mild to moderate excema or as directed by a physician. Store at room temperature.

☐Inactive Ingredients:

water (aqua), vegetable glycerin, caprylic/capric/triglyceride, simmondsia chinensis (jojoba) seed oil*, butyrospermum parkii (shea butter), cetyl alcohol, aloe vera barbadensis leaf juice*, symphytum officinale leaf extract, phenoxyethanol, xanthan gum, caprylyl glycol, calendula officinalis flower oil, avena sativa (oat) kernel extract, bisabolol, anthemis nobilis (chamomile) flower extract*.

*certified organic



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colloidal oatmeal cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42957-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OATMEAL (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y)	OATMEAL	1.25 g in 125 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
JOJOBA OIL (UNII: 724GKU717M)	
SHEA BUTTER (UNII: K49155WL9Y)	
CETYL ALCOHOL (UNII: 936JST6JCN)	

ALOE VERA LEAF (UNII: ZY81Z83H0X)	
COMFREY LEAF (UNII: DG4F8T839X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
LEVOMENOL (UNII: 24WE03BX2T)	
CHAMAEMELUM NOBILE FLOWER (UNII: O2T154T6OG)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42957-002-02	1 in 1 BOX		
1	NDC:42957-002-01	125 g in 1 TUBE		
2	NDC:42957-002-03	4 g in 1 POUCH		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	03/25/2013	

Labeler - Expro3, LLC (014904067)

Establishment			
Name	Address	ID/FEI	Business Operations
EL Erman Manufacturing, Ltd.		531894152	manufacture(42957-002)