

**COLLOIDAL OATMEAL- colloidal oatmeal cream**  
**H E B**

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**HEB Hill Country\_HCF 601.001/601AC**  
**Baby Eczema Therapy Cream**

**Active ingredient**

Colloidal oatmeal 1%

**Purpose**

Skin protectant

**Uses**

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

- eczema
- rashes

**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 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 right away.

**Directions**

apply as needed

**Other information**

store at room temperature

## **Inactive ingredients**

water, glycerin, distearyldimonium chloride, petrolatum, isopropyl palmitate, cetyl alcohol, dimethicone, panthenol, Avena sativa (oat) kernel oil, steareth-20, benzalkonium chloride, ceramide NP, sodium chloride, benzyl alcohol, sodium hydroxide

## **adverse reactions**

We hope you are satisfied with this product. If not, we will cheerfully refund your money.

DISTRIBUTED BY: H-E-B<sup>®</sup>, SAN ANTONIO, TX 78204

MADE IN THE USA WITH U.S. AND FOREIGN COMPONENTS

LOT NUMBER: ON PACKAGE

QUESTIONS OR COMMENTS? CALL TOLL FREE 1-888-593-0593

## **principal display panel**

HILL COUNTRY™

ESSENTIALS

Baby Eczema

Therapy Cream

COLLOIDAL OATMEAL

SKIN PROTECTANT

FREE FROM

- parabens
- phthalates
- dyes

NET WT. 5 OZ CONT. NET. 141 g

|  |                      |
|--|----------------------|
| <b>Drug Facts</b>  |                      |
| <b>Active ingredient</b>   | <b>Purpose</b>       |
| Colloidal oatmeal 1%   | Skin protectant      |
| <b>Uses</b> temporarily protects and helps relieve minor skin irritation and itching due to:<br><input type="checkbox"/> eczema <input type="checkbox"/> rashes  |                      |
| <b>Warnings</b>  |                      |
| For external use only  |                      |
| When using this product <input type="checkbox"/> do not get into eyes  |                      |
| Stop use and ask a doctor if <input type="checkbox"/> condition worsens <input type="checkbox"/> symptoms last more than 7 days or <input type="checkbox"/> 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 right away.   |                      |
| <b>Directions</b> apply as needed  |                      |
| <b>Other information</b> store at room temperature   |                      |
| <b>Inactive ingredients</b> water, glycerin, distearyldimonium chloride, petrolatum, isopropyl myristate, cetyl alcohol, panthenol, dimethicone, Avena sativa (oat) kernel oil, steareth-20, Avena sativa (oat) kernel extract, benzocaine, ceramide NP, sodium chloride, benzyl alcohol, sodium hydroxide.  |                      |
| <b>Información del Medicamento</b>   |                      |
| <b>Ingrediente activo</b>  | <b>Propósito</b>     |
| Avena coloidal 1%  | Protector de la piel |
| <b>Usos</b> temporalmente protege y ayuda a aliviar la irritación y picazón de la piel debido a:<br><input type="checkbox"/> eczema <input type="checkbox"/> erupciones  |                      |
| <b>Advertencias</b>  |                      |
| Para uso externo solamente   |                      |
| Cuando utilice este producto <input type="checkbox"/> evite el contacto con los ojos   |                      |
| Suspenda su uso y consulte a un médico si <input type="checkbox"/> la condición empeora <input type="checkbox"/> los síntomas duran más de 7 días o <input type="checkbox"/> desaparecen y ocurren de nuevo dentro de unos días  |                      |
| Mantener fuera del alcance de los niños. En caso de ingestión, obtenga ayuda médica o comuníquese con un Centro de Control de Envenenamiento de inmediato.   |                      |
| <b>Instrucciones</b> aplicar según sea necesario   |                      |
| <b>Otra información</b> almacenar a temperatura ambiente   |                      |
| <b>Ingredientes inactivos</b> agua, glicerina, cloruro de disteardimonio, vaselina, permitato de isopropilo, alcohol cetílico, panthenol, dimeticona, aceite de almendra de avena (avena sativa), estearato-20, extracto de almendra de avena (avena sativa), cloruro de benzocaino, ceramida NP, cloruro de sodio, alcohol bencílico, hidróxido de sodio. |                      |

We hope you are satisfied with this product. If not, we will cheerfully refund your money.  
 DISTRIBUTED BY: HILL COUNTRY ESSENTIALS, INC. SAN ANTONIO, TX 78204 • MADE IN THE USA WITH U.S. AND FOREIGN COMPONENTS • LOT NUMBER, EXPIRATION DATE, AND FOREVER COMPONENTS: LOT NUMBER: 1-488-400-0080

IMPORTADO Y DISTRIBUIDO POR: ESSENCIALES INTERNACIONALES H-C-400, S.A. DE C.V. AVENIDA PUE 2405 COL. OBISPO, C.P. 64080 MONTERREY, NL, MEXICO  
 HECHO EN USA DE MATERIALES DE USA Y OIBEN MEXICANA • NÚMERO DE LOTE: VEA ENVASE • PRESENTACIÓN: 1-488-400-0080 (SOLO EN USA)



# Baby Eczema Therapy Cream

COLLOIDAL OATMEAL SKIN PROTECTANT

# Crema de Terapia para Bebés con Eczema

AVENA COLOIDAL PROTECTOR DE LA PIEL



NET WT. 5 OZ  
CONT. NET. 141 g



## PRINCIPAL DISPLAY PANEL

HILL COUNTRY FARE<sup>®</sup>

Baby Eczema

Therapy Cream

COLLOIDAL OATMEAL

SKIN PROTECTANT

FREE FROM

- parabens
- phthalates
- dyes

NET WT. 5 OZ CONT. NET. 141 g

**Drug Facts**

**Active Ingredient** Colloidal oatmeal 1% **Purpose** Skin protectant

**Uses** temporarily protects and helps relieve minor skin irritation and itching due to: eczema, rashes

**Warnings**  
For external use only  
When using this product do not get into eyes  
Stop use and ask a doctor if condition worsens or 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 right away.

**Directions** apply as needed

**Other information** store at room temperature

**Inactive ingredients** water, glycerin, distearyltrimonium chloride, petrolatum, isopropyl palmitate, cetyl alcohol, dimethicone, parthenol, Avena sativa (oat) kernel oil, steareth-20, benzalkonium chloride, ceramide NP, sodium chloride, benzyl alcohol, sodium hydroxide

**Información del Medicamento**

**Ingrediente activo** Avena coloidal 1% **Propósito** Protector de la piel

**Usos** temporalmente protege y ayuda a aliviar la irritación y picazón de la piel debido a: eccema, erupciones

**Advertencias**  
Para uso externo solamente  
Cuando utilice este producto evite el contacto con los ojos  
Suspenda su uso y consulte a un médico si la condición empeora, los síntomas duran más de 7 días o desaparecen y ocurren de nuevo dentro de unos días  
Mantener fuera del alcance de los niños. En caso de ingestión, obtenga ayuda médica o comuníquese con un Centro de Control de Envenenamiento de Inmadiato.

**Instrucciones** aplicar según sea necesario

**Otra información** almacenar a temperatura ambiente

**Ingredientes inactivos** AGUA, GLICERINA, CLORURO DE DISTEARILDIMONIUM, PETROLATO, PALMITATO DE ISOPROPIL, ALCOHOL CETILICO, DIMETICONA, PARITENOL, ACEITE DE SEMILLA DE AVENA (AVENA SATIVA), ESTEARAT-20, CLORURO DE BENZALCONIO, CERAMIDA NP, CLORURO DE SODIO, ALCOHOL BENCILICO, HIDROXIDO DE SODIO.

We hope you are satisfied with this product. If not, we will cheerfully refund your money. DISTRIBUTED BY: H&M-PH, SAN ANTONIO, TX 78204  
MADE IN THE USA WITH U.S. AND FOREIGN COMPONENTS • LOT NUMBER • ON PACKAGE • QUESTIONS OR COMMENTS? CALL TOLL FREE 1-888-999-9999

IMPORTADO Y DISTRIBUIDO POR: SUPERMERCADOS INTERNACIONALES S.A.S. DE CALLE 140 #17E 2466 COL. OBRAJAL, C.A. BARRIO MONTERREY, A.L. MOXICO  
HECHO EN UNA DE NUESTRAS PLANTAS EN EL MUNDO • NÚMERO DE LOTE VER ENVASE • PREGUNTAS O COMENTARIOS LLAME GRATIS AL 1-888-999-9999 (SÓLO EN ESPAÑOL)



# Baby Eczema Therapy Cream

COLLOIDAL OATMEAL SKIN PROTECTANT

## Crema de Terapia para Bebés con Eczema

AVENA COLOIDAL PROTECTOR DE LA PIEL



NET WT. 5 OZ  
CONT. NET. 141 g



## COLLOIDAL OATMEAL

colloidal oatmeal cream

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:37808-128 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength     |
|---|-------------------|--------------|
| <b>OATMEAL</b> (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y) | OATMEAL           | 10 mg in 1 g |

### Inactive Ingredients

| Ingredient Name                                       | Strength |
|---|----------|
| <b>WATER</b> (UNII: 059QF0KO0R)                       |          |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                    |          |
| <b>DISTEARYLDIMONIUM CHLORIDE</b> (UNII: OM9573Z X3X) |          |
| <b>PETROLATUM</b> (UNII: 4T6H12BN9U)                  |          |
| <b>ISOPROPYL PALMITATE</b> (UNII: 8CRQ2TH63M)         |          |
| <b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)               |          |
| <b>DIMETHICONE, UNSPECIFIED</b> (UNII: 92RU3N3Y1O)    |          |

|   |  |
|---|--|
| <b>PANTHENOL</b> (UNII: W9CM0O67Z)              |  |
| <b>OAT KERNEL OIL</b> (UNII: 3UVP41R77R)        |  |
| <b>STEARETH-20</b> (UNII: L0Q8IK9E08)           |  |
| <b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) |  |
| <b>CERAMIDE NP</b> (UNII: 4370DF050B)           |  |
| <b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)       |  |
| <b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)        |  |
| <b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)      |  |

### Packaging

| # | Item Code        | Package Description                                | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:37808-128-28 | 141 g in 1 TUBE; Type 0: Not a Combination Product | 04/11/2019           |                    |

### Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M016                                     | 04/11/2019           |                    |

**Labeler** - H E B (007924756)

**Registrant** - Nice-Pak Products, LLC (119091520)

### Establishment

| Name                   | Address | ID/FEI    | Business Operations    |
|------------------------|---------|-----------|------------------------|
| Nice-Pak Products, LLC |         | 119091514 | manufacture(37808-128) |