SOOTHING BATH TREATMENT - colloidal oatmeal powder Triad Group

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 (in each packet)

Colloidal Oatmeal, 100%

PURPOSE

Skin Protectant

USE

temporarily protects and helps relieve minor skin irritation and itching due to one or more of the following:

- rashes
- eczema
- poison ivy, oak, or sumac
- insect bites

WARNINGS

For external use only.

When using this product

- do not get into eyes
- in some skin conditions, soaking too long may overdry
- to avoid slipping, use mat in tub or shower

Stop use and ask 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

- Turn warm water faucet on to full force.
- Slowly sprinkle 1 packet of colloidal oatmeal directly under the faucet into the tub or container.

- Stir any colloidal oatmeal that may have settled to the bottom.
- Soak affected area for 15-30 minutes as needed or as directed by a doctor.
- Pat dry (do not rub) to keep a thin layer on the skin.

CARTON INFORMATION

Soothe and Bathe

*Compare to active ingredient of Aveeno®

Soothing
Bath Treatment
100% Colloidal Oatmeal

Skin Protectant

For fast, soothing relief of poison ivy, poison sumac, poison oak, insect bites, rashes and eczema

REGULAR FORMULA Fragrance Free

8 Single use Packets - 1.5 oz. (42.5 g) each Total Net Wt. 12 oz. (340 g)

*This product is not manufactured or distributed by Johnson and Johnson, owner of the registered trademark, Aveeno®.

Triad Group, Inc. Brookfield, WI 53045 MADE IN USA www.triad-group.net

Fragrance Free Not Tested on Animals



SOOTHING BATH TREATMENT

colloidal oatmeal powder

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:50730-7100

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength
OATMEAL (UNII: 8 PI54V663Y) (OATMEAL - UNII:8 PI54V663Y)
OATMEAL (UNII: 8 PI54V663Y) OATMEAL 1 g in 1 g

| Packaging | | | | | |
|--------------------|---------------------|-----------------------------|--------------------|--|--|
| # Item Code | Package Description | Marketing Start Date | Marketing End Date | | |
| 1 NDC:50730-7100-1 | 8 in 1 CARTON | | | | |
| 1 | 42.5 g in 1 PACKET | | | | |

| Marketing Information | | | | | | |
|-----------------------|--|----------------------|--------------------|--|--|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | | | |
| OTC monograph final | part347 | 11/0 1/19 9 5 | | | | |
| | | | | | | |

Labeler - Triad Group (050259597)

| Establishment | | | | | | | |
|---------------|---------|-----------|---------------------|--|--|--|--|
| Name | Address | ID/FEI | Business Operations | | | | |
| Triad Group | | 050259597 | manufacture | | | | |

Revised: 2/2010 Triad Group