

## **HOMEOPATHIC BURN- white oxide of arsenic, pot marigold, spanish fly, stinging nettle cream**

### **Indiana Botanic Gardens**

*Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.*

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### **Homeopathic Burn Cream**

#### **Drug Facts**

##### **Active Ingredients**

White oxide of arsenic 10X H.P.U.S.\*

Pot Marigold 10X H.P.U.S.\*

Spanish Fly 10X H.P.U.S.\*

Stinging nettle 10X H.P.U.S.\*

##### **Purpose**

\*\*BR

\*\*BR

\*\*BR

\*\*BR

\*The letters H.P.U.S. indicate that the components in this product are officially monographed in the Homeopathic Pharmacopoeia of the U.S. \*\*The letters BR indicate Burn Relief.

##### **Other Ingredients:**

D.I. Water, Emulsifying Wax, Caprylic/Capric Triglyceride, Propylene Glycol, Mineral Oil, Triethanolamine, Carbomer and Imidazolidinyl urea.

##### **Directions:**

Apply directly to affected area, repeat as necessary.

##### **Drug Facts (cont.)**

##### **Uses:**

Use on affected area for relief of irritation, scalded skin, and generalized burns

##### **WARNING:**

- for external use only
- Avoid contact with the eyes. If contact occurs, rinse eyes thoroughly with water
- Keep out of reach of children
- If condition worsens or does not improve after regular use of this product as directed or if local

irritation or rash occurs, discontinue use and consult a physician.

Use only if seal is unbroken.

**Other Information:**

Any Questions?

1-800-644-8327

Website:

BotanicChoice.com

**Distributed by:**

Indiana Botanic Gardens, Inc. 3401 W. 37th Avenue Hobart, IN 46342

**Homeopathic Burn Cream**

For generalized burns or scalded skin

1 oz.

|   |  |  |   |
|---|--|--|---|
| <br>Drug Facts | <b>Active Ingredient Purpose</b><br>White oxide of arsenic 10X H.P.U.S.* **BR<br>Pot Marigold 10X H.P.U.S.* **BR<br>Spanish Fly 10X H.P.U.S.* **BR<br>Stinging nettle 10X H.P.U.S.* **BR<br>*The letters H.P.U.S. indicate that the components in this product are officially monographed in the Homeopathic Pharmacopoeia of the U.S. **The letters BR indicate Burn Relief.<br><b>Other Ingredients:</b> D.I. Water, Emulsifying Wax, Caprylic, Capric Triglyceride, Propylene Glycol, Mineral Oil, Triethanolamine, Citrus Aurantium, Benzocaine, Fragrance, Colorant, Preservative, etc.<br><b>Directions:</b> Apply directly to affected area, repeat as necessary. | <br><b>Burn Cream</b><br>For generalized burns or scalded skin<br>1 oz. | <b>Drug Facts (cont.)</b><br>Use: Use on affected area for relief of irritation, scalded skin, and generalized burns.<br><b>WARNING:</b> • For external use only • Avoid contact with the eyes. If contact occurs, rinse eyes thoroughly with water. • Keep out of reach of children • If condition worsens or does not improve after regular use of this product as directed or if a rash occurs, discontinue use and consult a physician. Use only if seal is unbroken.<br><b>Other Information:</b><br>Any Questions? 1-800-644-8327<br>Website: BotanicChoice.com<br>Distributed by: Indiana Botanic Gardens, Inc. 3401 W. 37th Avenue Hobart, IN 46342 |
|---|--|--|---|

| HOMEOPATHIC BURN   |                              |                    |               |
|--|------------------------------|--------------------|---------------|
| white oxide of arsenic, pot marigold, spanish fly, stinging nettle cream                         |                              |                    |               |
| Product Information  |                              |                    |               |
| Product Type   | HUMAN OTC DRUG               | Item Code (Source) | NDC:10578-003 |
| Route of Administration  | TOPICAL                      |                    |               |
| Active Ingredient/Active Moiety  |                              |                    |               |
| Ingredient Name  | Basis of Strength            | Strength           |               |
| ARSENIC TRIOXIDE (UNII: S7V92P67HO) (ARSENIC TRIOXIDE - UNII:S7V92P67HO)                         | ARSENIC TRIOXIDE             | 10 [hp_X] in 28 g  |               |
| CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD) (CALENDULA OFFICINALIS FLOWER - UNII:P0M7O4Y7YD) | CALENDULA OFFICINALIS FLOWER | 10 [hp_X] in 28 g  |               |
| LYTTA VESICATORIA (UNII: 3Q034RO3BT) (LYTTA VESICATORIA - UNII:3Q034RO3BT)                       | LYTTA VESICATORIA            | 10 [hp_X] in 28 g  |               |
| URTICA URENS (UNII: IHN2NQ5OF9) (URTICA URENS - UNII:IHN2NQ5OF9)                                 | URTICA URENS                 | 10 [hp_X] in 28 g  |               |
| Inactive Ingredients   |                              |                    |               |
| Ingredient Name  | Strength                     |                    |               |
| WATER (UNII: 059QF0KO0R)   |                              |                    |               |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)   |                              |                    |               |

|                                      |  |
|--------------------------------------|--|
| POLYSORBATE 60 (UNII: CAL22UVI4M)    |  |
| TRICAPRYLIN (UNII: 6P92858988)       |  |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)  |  |
| MINERAL OIL (UNII: T5L8T28FGP)       |  |
| TROLAMINE (UNII: 9O3K93S3TK)         |  |
| CARBOMER 934 (UNII: Z135WT9208)      |  |
| DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4) |  |

| Product Characteristics |       |              |  |
|-------------------------|-------|--------------|--|
| Color                   | WHITE | Score        |  |
| Shape                   |       | Size         |  |
| Flavor                  |       | Imprint Code |  |
| Contains                |       |              |  |

| Packaging |                  |                     |                      |                    |
|-----------|------------------|---------------------|----------------------|--------------------|
| #         | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
| 1         | NDC:10578-003-01 | 28 g in 1 JAR       |                      |                    |

| Marketing Information  |  |                      |                    |
|------------------------|--|----------------------|--------------------|
| Marketing Category     | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| unapproved homeopathic |  | 04/27/2012           |                    |

**Labeler** - Indiana Botanic Gardens (005421771)

**Registrant** - Indiana Botanic Gardens (005421771)

| Establishment       |         |           |                        |
|---------------------|---------|-----------|------------------------|
| Name                | Address | ID/FEI    | Business Operations    |
| ASI Marketing Group |         | 964366611 | manufacture(10578-003) |