

BURN - aesculus hippocastanum, aloe socotrina, arnica montana, berberis vulgaris, calendula officinalis, salicylicum acidum, zincum metallicum spray
MBI Distributing Inc.

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.

Aesculus hippocastanum 4x, Aloe socotrina 4x, Arnica montana 4x, Berberis vulgaris 4x, Calendula officinalis 4x, Salicylicum acidum 2x, Zincum metallicum 3x

deionized water, propylene glycol, polysorbate 20, glycerine, sodium bicarbonate, MSM, Dimethylaminoethanol, citric acid, potassium sorbate, benzyl alcohol, trace minerals (iron), avocado oil, and vitamin E

Temporarily relieves symptoms of minor burns, superficial scalds, sunburn, and other minor skin irritations such as:

- redness
- stinging
- burning
- itching
- minor pain
- dryness
- as per homeopathic materia medica

Directions

- Adults and children 3 years of age and older:
- clean the burned area(s)
- apply topically as needed not more than 12 times daily
- area may be covered with a sterile bandage
- children under 3 years of age: consult a physician

Aesculus hippocastanum.....Venous Stasis
Aloe socotrina.....Redness
Arnica montana.....Burning
Berberis vulgaris.....Burning
Calendula officinalis.....Healing
Salicylicum acidum.....Burning and Heat
Zincum metallicum.....Pain Reliever

Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

For external use only.

Questions?

1.800.321.3740
Mon-Fri, 9am-5pm

Drug Facts (continued)

When using this product

- use only as directed
- test on a small area before use. This product may cause allergic reaction in some individuals.
- wash hands before and after using
- avoid contact with eyes or mucous membranes
- do not bandage tightly

Stop use and ask a doctor if

- condition worsens
- if symptoms persist for more than 7 days or clear up and occur again within a few days
- excessive skin irritation occurs

If pregnant or breast feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Adults and children 3 years of age and older:
- clean the burned area(s)
- apply topically as needed not more than 12 times daily
- area may be covered with a sterile bandage
- children under 3 years of age: consult a physician

Temporary relief for symptoms of minor burns, superficial scalds, sunburn, and other minor skin irritations such as: redness, stinging, burning, itching and dryness; as well as minor pain.

Drug Facts (continued)

Other Information

- store at room temperature
- Tamper Evident: Do not use if imprinted seal around cap is broken or missing.

Inactive Ingredients: Benzyl Alcohol, Citric Acid, Dimethyl MEA, Dimethyl Sulfone, Glycerin, Persea Gratissima (Avocado) Oil, Polysorbate 20, Potassium Sorbate, Propylene Glycol, Sodium Bicarbonate, Tocopherol, Trona, Water

Questions?
1.800.321.3740
Mon-Fri, 9am-5pm

MBI Distributing, Inc.
211 N 1800 W
Lindon, UT 84042



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NDC: 58301-181-28



Burn Spray

Homeopathic Topical Spray for minor skin burns

Patent Pending

2 fl oz (60 ml)

Drug Facts

Active Ingredients Purpose

| | | |
|---------------------------|-------|-------------------------|
| Aesculus hippocastanum 4X | | Venous Stasis |
| Aloe socotrina 4X | | Redness |
| Arnica montana 4X | | Burning |
| Berberis vulgaris 4X | | Burning |
| Calendula officinalis 4X | | Healing |
| Salicylicum acidum 2X | | Burning & Heat Reliever |
| Zincum metallicum 3X | | Pain Reliever |

Uses Temporarily relieves symptoms of minor burns, superficial scalds, sunburn, and other minor skin irritations such as: redness • stinging • burning • itching • minor pain • dryness • as per homeopathic materia medica

Warnings
For external use only.

Do not

- use if you are allergic to salicylates (although this product does not contain aspirin)
- use in the eyes
- apply over large areas of the body
- use longer than 1 week unless directed by a doctor
- ingest

Ask a doctor before use in case of deep or puncture wounds, animal bites, or serious burns.

Do not

- use if you are allergic to salicylates (although this product does not contain aspirin)
- use in the eyes
- apply over large areas of the body
- use longer than 1 week unless directed by a doctor
- ingest

Ask a doctor before use in case of deep or puncture wounds, animal bites, or serious burns.

When using this product

- use only as directed
- test on a small area before use. This product may cause allergic reaction in some individuals.
- wash hands before and after using
- avoid contact with eyes or mucous membranes
- do not bandage tightly

Stop use and ask a doctor if

- condition worsens
- if symptoms persist for more than 7 days or clear up and occur again within a few days
- excessive skin irritation occurs
- store at room temperature
- Tamper Evident: Do not use if imprinted seal around cap is broken or missing.

BURN

aesculus hippocastanum, aloe socotrina, arnica montana, berberis vulgaris, calendula officinalis, salicylicum acidum, zincum metallicum spray

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:58301-181 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--|----------------------|
| AESCULUS HIPPOCASTANUM FLOWER (UNII: KK0Z92II8M) (AESCULUS HIPPOCASTANUM FLOWER - UNII:KK0Z92II8M) | AESCULUS HIPPOCASTANUM FLOWER | 4 [hp_X] in 60 mL |
| ALOE (UNII: V5VD430YW9) (ALOE - UNII:V5VD430YW9) | ALOE | 4 [hp_X] in 60 mL |
| ARNICA MONTANA (UNII: O80TY208ZW) (ARNICA MONTANA - UNII:O80TY208ZW) | ARNICA MONTANA | 4 [hp_X] in 60 mL |
| BERBERIS VULGARIS ROOT BARK (UNII: 1TH8Q20J0U) (BERBERIS VULGARIS ROOT BARK - UNII:1TH8Q20J0U) | BERBERIS VULGARIS ROOT BARK | 4 [hp_X] in 60 mL |
| CALENDULA OFFICINALIS FLOWERING TOP (UNII: 18E7415PXQ) (CALENDULA OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ) | CALENDULA OFFICINALIS FLOWERING TOP | 4 [hp_X] in 60 mL |
| SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ) | SALICYLIC ACID | 2 [hp_X] in 60 mL |
| ZINC SULFATE HEPTAHYDRATE (UNII: N57J12K7WP) (ZINC CATION - UNII:13S1S8SF37) | ZINC SULFATE HEPTAHYDRATE | 3 [hp_X] in 60 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| WATER (UNII: 059QF0K00R) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| POLYSORBATE 20 (UNII: 7T1F30V5YH) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| SODIUM BICARBONATE (UNII: 8MDF5V39QO) | |
| DIMETHYL SULFONE (UNII: 9H4PO4Z4FT) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | |
| BENZYL ALCOHOL (UNII: LKG8494WBH) | |
| AVOCADO OIL (UNII: 6VNO72PFC1) | |
| ALPHA-TOCOPHEROL (UNII: H4N855PNZ1) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--------------------------|----------------------|--------------------|
| 1 | NDC:58301-181-28 | 60 mL in 1 BOTTLE, SPRAY | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|------------------------|--|----------------------|--------------------|
| unapproved homeopathic | | 09/01/2010 | |

Labeler - MBI Distributing Inc. (196786545)

Registrant - MBI Distributing Inc. (196786545)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------|---------|-----------|---------------------|
| MBI Distributing Inc. | | 196786545 | manufacture |

Revised: 7/2011

MBI Distributing Inc.