MEDIFLEX - menthol cream SAS Group Inc.

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.

Menthol 5%

Topical Analgesic

For the temporary relief of minor aches and pains of muscles and joints associated with arthritis, simple backache, sprains, bruises and strains.

For external use only.

Do not use:

- on wounds or damaged skin
- with a heading pad

Ask a doctor before use if you are:

- prone to allergic reactions to salicylates, including aspirin
- using a product on a child under 12 years of age

When using this product:

- avoid contact with eyes and mucous membranes
- use only as directed
- 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 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 12 years of age and older: apply to affected area not more than 3 to 4 times daily
- Children under 12 years of age: consult a physician
- Apply generously and massage into affected area until completely absorbed
- Apply before and after sports or exercise to help soothe aching muscles and muscle strain
- Repeat as needed up to four times per day

Store at 20 to 25 degrees Celsius (68 to 77 degrees F)

Aloe, Avocado Oil, Ceteareth-20, Cylcomethicone, Grape Seed Oil, MediFlex Relief Proprietary Herbal Extract Blend (juniper [berry], European Goldenrod [flower], Dandelion [leaf], Meadowsweet [herb], White Willow [bark], Methyl Glucose Sesquisterate, Natural Oil of Wintergreen, Phenoxyethanol Methylparaben, Shea Butter, Steareth-2, Stearath-10, Stearic Acid, Water

Questions or comments? 1-877-309-8118 Monday through Friday, 9am-5pm.

This product is manufactured exclusively for: SAS Group, Inc., Tarrytown, NY 10591

Temporary Pain Relief

Mediflex Relief Cream

Temporary Relief of Minor Aches and Pains Associated with Arthritis, Simple Backache, Sprains, Bruises and Strains.

- Soothing and medicated topical analgesic for aching joints and muscles
- Effective for pre-exercise warm-up
- Deep penetrating therapeutic pain relief
- With skin moisturizing conditions aloe, shea butter, avocado, and grape seed oil
- Contains MediFlex Relief's clinically tested herbal formula



Drug Facts Active Ingredients Purpose Topical Analgesis Uses For the temporary relief of minor aches and pains of muscles and joints associated with arthritis, simple backache, sprains bruises and strain: Warnings For external use only. Do not use: . On wounds or damaged skin. . With a heating pad. Ask a doctor before use if you are: . Prone to allergic reactions to salicylates, including aspirin. . Using product on a child under 12 years of age. When using this product: · Avoid contact with eyes and mucous membranes. · Use only as directed. · 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 center right away.

Drug Facts (continued)

Directions

- Adults and children 12 years of age and older: apply to affected area not more than 3 to 4 times daily.
- . Children under 12 years of age: consult a physician.
- Apply generously and massage into affected area until completely absorbed.
 Apply before and after sports or exercise to help soothe aching muscles and muscle strain.
- . Repeat as needed up to four times per day.

Other information

Store at 20" to 25°C (68" to 77"F).

Inactive Ingredients:

Aloe, Avocado Oil, Ceteareth-20, Cyclomethicone, Grape Seed Oil, MediFlex™ Relief Proprietary Herbal Extract Blend (Juniper [berry], European Goldenrod [flower], Dandelion [leaf], Meadowsweet [herb], White Willow[bark]), Methyl Glucose Sesquistearate, Natural oil of Wintergreen, Phenoxyethanol Methylparaben, Shea Butter, Steareth-2, Steareth-10, Stearic Acid. Water.

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MEDIFLEX

menthol cream

| Product Information | | | | |
|-------------------------|----------------|--------------------|---------------|--|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:67662-001 | |
| Route of Administration | TOPICAL | | | |

| Active Ingredient/Active Moiety | | | |
|--|-------------------|-----------|--|
| Ingredient Name | Basis of Strength | Strength | |
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 5 in 85 g | |

| Packaging | | | |
|--------------------|---------------------|----------------------|--------------------|
| # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 NDC:67662-001-03 | 85 g in 1 JAR | | |

| Marketing Information | | | | |
|-------------------------|--|----------------------|--------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | part348 | 03/29/2010 | | |
| | | | | |

Labeler - SAS Group Inc. (948174057)

Registrant - SAS Group Inc. (948174057)

| Establishment | | | |
|----------------|---------|-----------|---------------------|
| Name | Address | ID/FEI | Business Operations |
| SAS Group Inc. | | 948174057 | relabel |

| Establishment | | | | |
|-----------------------|---------|-----------|---------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Accupack Midwest Inc. | | 139637433 | manufacture | |

Revised: 4/2010 SAS Group Inc.