

ASPER-FLEX CREAM- trolamine salicylate cream
Geritrex LLC

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.

Asper-Flex Cream

Drug Facts

Active Ingredients.....Purpose
Trolamine Salicylate(10%).....Topical Analgesic

Uses

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

Directions

Apply generously to affected area. Massage into painful area until thoroughly absorbed into skin. Repeat as necessary, but not more than 4 times daily.

No more than 4 times daily.

Warnings

• Use only as directed • If prone to allergic reaction from aspirin or salicylate, consult a doctor • If redness is present, discontinue use and consult a doctor • If condition worsens or if pain persists for more than 7 days or clears up and occurs again within a few days, discontinue use and consult a doctor • Avoid contact with eyes • As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product
Do not use: • On children under 10 years of age • If skin is irritated or if irritation develops • **KEEP THIS AND ALL MEDICINE OUT OF THE REACH OF CHILDREN** • In case of accidental ingestion, seek professional assistance or contact a poison control center immediately

Other Ingredients

Aloe Vera Gel, Alpha Tocopherol, Cetyl Alcohol, Glycerin, DMDM Hydantoin, Methylparaben, Mineral Oil, Propylene Glycol, Propylparaben, Stearic Acid, Triethanolamine, Water

Storage

At room temperature 15°-30° C (59°-86° F).

Close cap tightly after use.

Keep out of reach of children

KEEP THIS AND ALL MEDICINE OUT OF THE REACH OF CHILDREN

NDC 54162-010-03



Asper-Flex Cream

Trolamine Salicylate 10%

With Vitamin E and Aloe Vera

Muscular Pain Relieving Cream

Net Wt. 3 oz (85g)

• Odor Free • No Methyl Salicylate • No Menthol • Aspirin Free

<p>Drug Facts</p> <p>Active ingredient Trolamine Salicylate 10%.....Topical analgesic</p> <p>Uses Temporarily relieves minor pain associated with: ■ arthritis ■ simple backache ■ muscle strains ■ sprains ■ bruises ■ cramps</p> <p>Warnings FOR EXTERNAL USE ONLY</p> <p>Allergy alert: If prone to allergic reaction from aspirin or salicylates, consult a doctor before use.</p> <p>When using this product: ■ use only as directed. Read and follow all directions and warnings on this label. ■ do not bandage tightly or apply local heat (such as heating pads) to the area of use ■ avoid contact with eyes and mucous membranes ■ do not apply to wounds or damaged, broken or irritated skin ■ do not use at the same time as other topical analgesics</p> <p>Stop use and ask a doctor if: ■ condition worsens ■ symptoms persist for more than 7 days or clear up and occur again within a few days ■ irritation develops ■ redness is present.</p> <p>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.</p>	<p>Directions adults and children over 12 years: ■ apply generously to affected area ■ massage into painful area until thoroughly absorbed into skin ■ repeat as necessary, but no more than 3 to 4 times daily</p> <p>children 12 years or younger: ask a doctor</p> <p>Other information Store at room temperature 15°-30° C (59°-86° F). Close cap tightly after use.</p> <p>Inactive ingredients aloe vera leaf, alpha tocopherol, cetyl alcohol, DDMH hydantoin, glycerin, methylparaben, mineral oil, propylene glycol, propylparaben, stearic acid, tetrahydroamine, water</p>
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Distributed by
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ASPER-FLEX CREAM

trolamine salicylate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54162-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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Trolamine Salicylate (UNII: H8O4040BHD) (salicylic acid - UNII:O414PZ4LPZ)		Trolamine Salicylate	8.5 g in 85 g	
Inactive Ingredients				
Ingredient Name				Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)				
CETYL ALCOHOL (UNII: 936JST6JCN)				
GLYCERIN (UNII: PDC6A3C0OX)				
DMDM HYDANTOIN (UNII: BYR0546TOW)				
METHYL PARABEN (UNII: A2I8C7HI9T)				
MINERAL OIL (UNII: T5L8T28FGP)				
PROPYL PARABEN (UNII: Z8IX2SC1OH)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TROLAMINE (UNII: 9O3K93S3TK)				
WATER (UNII: 059QF0K00R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54162-010-03	85 g in 1 TUBE; Type 0: Not a Combination Product	07/31/2015	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	07/31/2015		

Labeler - Geritrex LLC (112796248)

Establishment

Name	Address	ID/FEI	Business Operations
Geritrex LLC		112796248	manufacture(54162-010)