

OSMOFLEX- menthol cream
Sarati International, Inc.

OsmoFlex-101

Drug Facts

Active Ingredient

Menthol 1.30%

Purpose

Topical Analgesic

Uses

For the temporary relief of minor aches and pains of muscles and joints associated with

- simple backache
- arthritis
- strains
- bruises
- sprains

Warnings

For External Use Only

Do not use

- on wounds or damaged skin
- with a heating pad

When using this product

- avoid contact with eyes or mucous membranes
- do not bandage tightly
- use only as directed

Stop Use and Ask A Doctor

- if conditions worsen or if symptoms persist for more that 7 days
- symptoms clear up and occur again within a few days
- excessive skin irritation.

If pregnant or breast feeding consult a doctor before use.

Keep out of reach of children

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center immediately.

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, ask a doctor
- massage a generous amount to affected area until absorbed.

Inactive Ingredients

acrylamide/sodium acryloyldimethyl taurate copolymer, caprylic/capric triglyceride, caprylyl glycol, cetyl alcohol, chondroitin sulfate, deionized water, glucosamine sulfate, glycerin, glycerol stearate, isohexadecane, lecithin, magnesium sulfate heptahydrate (epsom salt), methylsulfonylmethane (msm), peg-100, stearate, phenoxyethanol, polyacrylate 13, polyisobutene, polysorbate 20, polysorbate 80, sd alcohol, shea butter, sorbic acid, stearic acid, xanthan gum

Questions

Call 1-866-984-3054

Other Information

- each gram contains magnesium 6.6 mg
- store and use at room temperature 20°-25° C (68°-77° F)
- tamper resistant-do not use if seal under cap is broken or missing.

OsmoFlex product label

OsmoFlex™

Pain Relieving Cream Menthol 1.3%

Net Wt 4 oz (113.4g)

NET WT 16 OZ (453.6 g)

NET WT 32 OZ (964.3 g)

Dist. by: Seablue Vitamins, LLC • 211 North Locksley Drive • Lafayette, LA 70508

www.seabluevitamins.com

PAIN RELIEVING CREAM
MENTHOL 1.3%

NET WT 16 OZ (453.6 g)

OSMOflex™

Drug Facts		Drug Facts (continued)	
Active Ingredient Menthol 1.30%	Purpose Topical Analgesic	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, ask a doctor ■ massage a generous amount to affected areas until absorbed	
Uses For the temporary relief of minor aches and pains of muscles and joints associated with ■ simple backache ■ arthritis ■ strains ■ bruises ■ sprains		Other information ■ each gram contains magnesium 6.6 mg ■ store at room temperature, 20°-25°C (68°-77°F) ■ tamper resistant-do not use if seal under cap is broken or missing.	
Warnings For external use only. Do not use ■ on wounds or damaged skin ■ with a heating pad Ask a doctor before use if you have ■ redness over affected area ■ kidney disease ■ a magnesium restricted diet ■ shellfish allergy When using this product ■ avoid contact with eyes or mucous membranes ■ do not bandage tightly ■ use only as directed Stop use and ask a doctor if ■ condition worsens or symptoms persist for more than 7 days ■ symptoms clear up and occur again within a few days ■ excessive skin irritation occurs If pregnant or breast feeding consult a doctor before use. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.		Inactive ingredients acrylamide/sodium acryloyldimethyl taurate copolymer, caprylic/capric triglyceride, caprylyl glycol, cetyl alcohol, chondroitin sulfate, deionized water, glucosamine sulfate, glycerin, glycerol stearate, isohexadecane, lecithin, magnesium sulfate heptahydrate (epsom salt), methylsulfonylmethane (msm), peg-100 stearate, phenoxyethanol, polyacrylate 13, polyisobutene, polysorbate 20, polysorbate 80, sd alcohol, shea butter, sorbic acid, stearic acid, xanthan gum	
		Questions? Call 1-866-984-3054 weekdays 9 AM -4 PM CST	
		<i>Dist. by: Seablue Vitamins, LLC • 211 North Locksley Drive • Lafayette, LA 70508</i> www.seabluevitamins.com	

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OSMOFLEX
menthol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67676-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1.3 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ACRYLAMIDE (UNII: 20R035KLCI)	
TRICAPRYLIN (UNII: 6P92858988)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CHONDROITIN SULFATE (BOVINE) (UNII: 6IC1M3OG5Z)	
WATER (UNII: 059QF0KO0R)	
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)	
GLYCERYL STEARATE CITRATE (UNII: WH8T92A065)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
MAGNESIUM SULFATE HEPTAHYDRATE (UNII: SK47B8698T)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
POLYOXYL 100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYISOBUTYLENE (1200000 MW) (UNII: FLT10CH37X)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
ALCOHOL (UNII: 3K9958V90M)	
SHEA BUTTER (UNII: K49155WL9Y)	
SORBIC ACID (UNII: X045WJ989B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67676-101-01	113.4 g in 1 TUBE; Type 0: Not a Combination Product	05/16/2016	
2	NDC:67676-101-04	453.6 g in 1 BOTTLE; Type 0: Not a Combination Product	05/16/2016	
3	NDC:67676-101-03	964.3 g in 1 BOTTLE; Type 0: Not a Combination Product	05/16/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	05/16/2016	

Labeler - Sarati International, Inc. (160219770)

Registrant - Sarati International, Inc. (160219770)

Establishment

Name	Address	ID/FEI	Business Operations
Sarati International, Inc.		160219770	manufacture(67676-101)

Revised: 10/2023

Sarati International, Inc.