FLEXILON- methyl salicylate, menthol, camphor cream
Semprae Laboratories 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.

ACTIVE INGREDIENT

Camphor 4%

Menthol 7.5%

Methyl Salicylate 10%

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 , broken or irritated skin
- with a heating pad

When using this product

- avoid contact with eyes or mucous membranes
- do not bandage tightly

Stop use and ask a doctor if

- condition worsens
- you have redness over the affected area
- symptoms persist for more than 7 days or symptoms clear up and occur within a few days

- excessive skin irritation occurs

Keep out of reach of children

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

DIRECTIONS

- use only as directed
- **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 doctor.

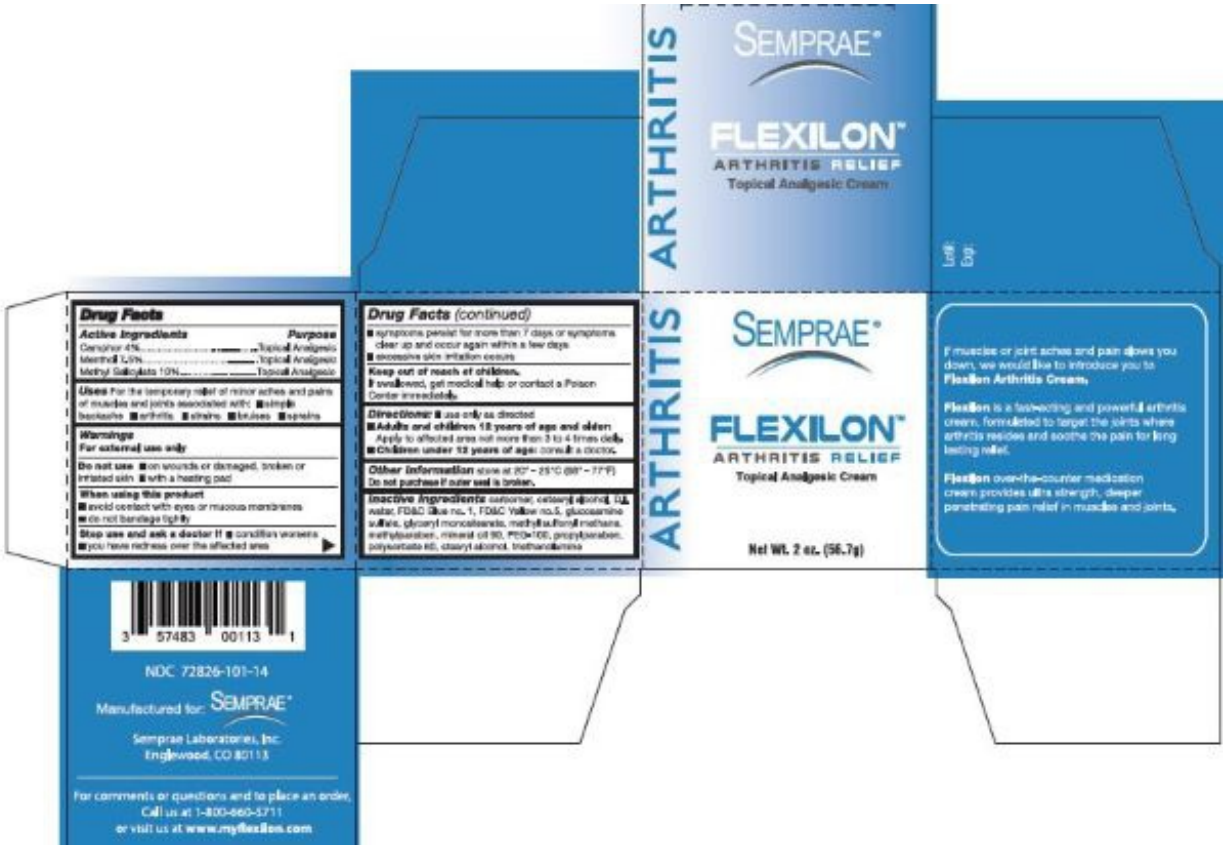
OTHER INFORMATION

store at 20-25C (68-77F)

Do not purchase if outer seal is broken

INACTIVE INGREDIENTS

carbomer, cetearyl alcohol, D.I. water, FD&C Blue no. 1, FD&C Yellow no.5, glucosamine sulfate, glyceryl monostearate, methyl sulfonyl methane, methylparaben, mineral oil 90, PEG-100, propylparaben, polysorbate 60, stearyl alcohol, triethanolamine



FLEXILON

methyl salicylate, menthol, camphor cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72826-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	7.5 g in 100 g
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	4 g in 100 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	10 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
MINERAL OIL (UNII: T5L8T28FGP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:72826-101-14	1 in 1 CARTON	11/10/2020	
1		56.7 g in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
OTC monograph not final	part348	11/10/2020	

Labeler - Semprae Laboratories Inc (093739668)

Registrant - Semprae Laboratories Inc (093739668)

Revised: 12/2022 Semprae Laboratories Inc