PHOENIX KINETICREAM ANTI-INFLAMMATORY AND PAIN RELIEF- menthol cream Phoenix Bioperformance Products, 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.

Phoenix KinetiCream Antiflammatory and Pain Releif Cream

Drug Facts

Active Ingredients

Menthol 2.00%

Purpose

Topical Pain Relief

Uses

temporary relieves of these symptoms:

- minor aches
- pains associated with simple backache
- arthritis
- bruises
- sprains
- cramps
- muscle strains.

Warnings

For external use only.

• Use only as directed children under 6 years, ask a doctor.

Stop use and ask a doctor if:

- condition worsen
- pain persist of more than 7 days
- irritation develops

Avoid contact with eyes and open wounds.

If swallowed, get medical help or contact your local Poison Control Center or emergency room immediately.

If pregnant or breast feeding

ask a health professional before use.

Keep out of reach of children.

Directions

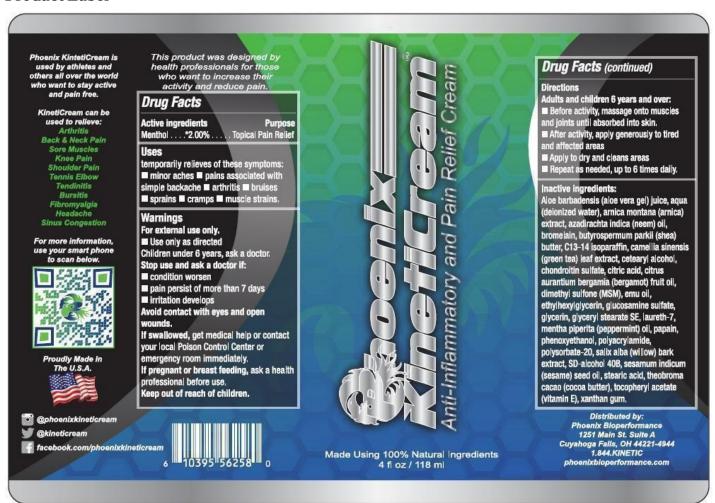
Adults and children 6 years and over:

- Before activity, massage onto muscles and joints until absorbed into skin.
- After activity, apply generously to tired and affected areas
- Apply to dry and cleans areas
- Repeat as needed, up to 6 times daily.

Inactive ingredients:

Aloe barbadensis (aloe vera gel) juice, aqua (deionized water), arnica montana (arnica) extract, azadirachta indica (neem) oil, bromelain, butyrospermum parkii (shea) butter, C13-14 isoparaffin, camellia sinensis (green tea) leaf extract, cetearyl alcohol, chondroitin sulfate, citric acid, citrus aurantium bergamia (bergamot) fruit oil, dimethyl sulfone (MSM), emu oil, ethylhexylglycerin, glucosamine sulfate, glycerin, glyceryl stearate SE, laureth-7, mentha piperita (peppermint) oil, papain, phenoxyethanol, polyacrylamide, polysorbate-20, salix alba (willow) bark extract, SD-Alcohol 40B, sesamum indicum (sesame) seed oil, stearic acid, theobroma cacao (cocoa butter), tocopheryl acetate (vitamin E), xanthan gum.

Product Label



PHOENIX KINETICREAM ANTI-INFLAMMATORY AND PAIN RELIEF

menthol cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58611-032
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	20 mg in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
WATER (UNII: 059QF0KO0R)		
ARNICA MONTANA (UNII: O80 TY20 8 ZW)		
BROMELAINS (UNII: U182GP2CF3)		
SHEA BUTTER (UNII: K49 155WL9 Y)		
C13-14 ISOPARAFFIN (UNII: E4F12ROE70)		
GREEN TEA LEAF (UNII: W2ZU1RY8B0)		
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)		
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)		
BERGAMOT OIL (UNII: 39 W1PKE3JI)		
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)		
EMU O IL (UNII: 344821WD61)		
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)		
GLUCO SAMINE SULFATE (UNII: 1FW7WLR731)		
GLYCERIN (UNII: PDC6A3C0OX)		
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)		
LAURETH-7 (UNII: Z95S6G8201)		
PEPPERMINT OIL (UNII: AV092KU4JH)		
PAPAIN (UNII: A236 A0 6 Y32)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
POLYSORBATE 20 (UNII: 7T1F30V5YH)		
WILLOW BARK (UNII: S883J9JDYX)		
SESAME OIL (UNII: QX10HYY4QV)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
COCOA BUTTER (UNII: 5120 YT1CRR)		
.ALPHATOCOPHEROL (UNII: H4N855PNZ1)		
XANTHAN GUM (UNII: TTV12P4NEE)		

ı	Packaging					
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
l	1 NDC:58611-032-04	118 mL in 1 TUBE; Type 0: Not a Combination Product	02/22/2017			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	05/22/2013		

Labeler - Phoenix Bioperformance Products, LLC (034681162)

Revised: 2/2017 Phoenix Bioperformance Products, LLC