

PAIN RELIEF CREAM- pain relief cream cream
Zhejiang Apelo Kangyu Pharmaceutical Co., Ltd.

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.

- External Analgesic
- Topical Analgesic
- Pain relieving cream

Children under 2 years of age: consult a doctor

Temporarily relieves minor aches and pains of muscles and joints associated with:

- simple backache
- arthritis
- strains
- bruises
- sprains

Do Not Use:

- on wounds
- on irritated or damaged skin
- otherwise than as directed

Adults and children 3 years of age and older: apply 3 to 4 drops of medicated oil to the affected area 1 to 2 times daily. After applying the product, a warm pad may be placed on the affected area for 10 minutes and then massaged as shown in the illustrations.

- Yellow Vaseline
- Wool Grease
- Liquid Paraffin
- Stearic Acid
- Glycerol
- Triethanolamine
- Ethylparaben
- Dimethyl Sulfoxide
- Radix Illicis Pubescentis
- Cortex Araliae
- Pheretima
- Herba Hedyotis Chrysotricae
- Radix Pini Massoniana
- Sophorae Flavescentis Radix
- Drynariae Rhizoma
- Radix Adinae Rubellae

- Radix Cudraniae Cochinchinensis
- Root from Itea Oblonga Hand.-Mazz
- Root from Syzygium Grijsii (Hance) Merr.Et
- Perry & Root from Ampelopsis Sinica (MIQ) W.T. Wang & Root from Ormosia Henryi Prain & Cuscuta Japonica Choisy
- Camphor 1%



PAIN RELIEF CREAM			
pain relief cream cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66653-100
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)		CAMPHOR (NATURAL)	1g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SOPHORA FLAVESCENS ROOT (UNII: IYR6K8KQ5K)	
MACLURA COCHINCHINENSIS ROOT (UNII: 3WTU9E1VPU)	
LANOLIN (UNII: 7EV65EAW6H)	
MINERAL OIL (UNII: T5L8T28FGP)	
ETHYL PARABEN (UNII: 14255EXE39)	
ILEX PUBESCENS ROOT (UNII: V5V22LFX73)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
DIMETHYL SULFOXIDE (UNII: YOW8V9698H)	
ARALIA CHINENSIS WHOLE (UNII: 4048809221)	
AMPELOPSIS GLANDULOSA VAR. BREVIPEDUNCULATA FRUIT (UNII: Y6SZ1HB5NG)	
PHERETIMA ASPERGILLUM (UNII: 1842H27PGA)	
PETROLATUM (UNII: 4T6H12BN9U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
OLDENLANDIA DIFFUSA (UNII: 291PPU5K9I)	
PINUS MASSONIANA LEAF (UNII: OFD5T4515T)	
DRYNARIA FORTUNEI ROOT (UNII: 731W842X8Q)	
ADINA RUBELLA WHOLE (UNII: 1S210XS3BZ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66653-100-01	30 g in 1 TUBE; Type 0: Not a Combination Product	04/05/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/05/2016	

Labeler - Zhejiang Apelo Kangyu Pharmaceutical Co., Ltd. (420823163)

Establishment

Name	Address	ID/FEI	Business Operations
Zhejiang Apelo Kangyu Pharmaceutical Co., Ltd.		420823163	manufacture(66653-100)

Revised: 4/2016

Zhejiang Apelo Kangyu Pharmaceutical Co., Ltd.