

BAROX S- camphor (synthetic), methyl salicylate, menthol gel
Barox 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.

ACTIVE INGREDIENT

Active ingredients: L-menthol 0.8%, DL-Camphor 5.9%, Methyl Salicylate 4.6%

INACTIVE INGREDIENT

Inactive Ingredients: Purified Water, Carbomer, Ethanol, Methyl Sulfonylmethane, Methyl Parahydroxybenzoate, Cetyl Palmitate, Avocado Oil, Polysorbate 80, Cetyl Alcohol, Aminomethyl Propanol

PURPOSE

Purpose: Topical Analgesic

WARNINGS

Warnings:

For external use only.

Avoid contact with eyes.

Keep this and all drugs out of the reach of children.

KEEP OUT OF REACH OF CHILDREN

Keep this and all drugs out of the reach of children.

Uses

Uses:

Barox S is an anti-inflammatory pain relieving and topical analgesic ointment that is intended to relieve muscle and joint pain associated with arthritis, rheumatism, backaches, knee pain, shoulder pain.

Direction

Direction:

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.

DESCRIPTION

DESCRIPTION:

Do not use : on wounds or damage skin

Stop use and ask a doctor Stop use and ask a doctor if excessive skin irritation occurs. Ask a doctor before use if you have redness over the affected area

Other Information : Store in a cool dry place with lid closed tightly

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



BAROX S

camphor (synthetic), methyl salicylate, menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55692-110
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	7.08 g in 120 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	5.52 g in 120 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.96 g in 120 g

Inactive Ingredients

Ingredient Name	Strength
-----------------	----------

Water (UNII: 059QF0KO0R)				
AVOCADO OIL (UNII: 6VNO72PFC1)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55692-110-01	120 g in 1 CARTON; Type 0: Not a Combination Product	03/01/2014	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	03/01/2014		

Labeler - Barox Co., Ltd. (688380051)

Registrant - Barox Co., Ltd. (688380051)

Establishment			
Name	Address	ID/FEI	Business Operations
Gdkcosmetics Co., Ltd.		557821946	manufacture(55692-110)

Revised: 9/2017

Barox Co., Ltd.