BAROX- menthol gel
KTAIGA 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 ingredient: Menthol 2.5%

Inactive ingredient

Inactive ingredients:
Water, Alcohol, Propylene Glycol, Germanium Dioxide, Allantoin, Carbomer, Triethanolamine, PEG-60 Hydrogenated Castor Oil, Disodium EDTA, Methylparaben

Purpose

Purpose: Topical Analgesic

Warnings

Warnings: For external use only

Keep out of reach of children

Keep out of reach of children:
Keep out of reach of children to avoid accidental ingestion.
If swallowed, get medical help or contact a Poison Control Center immediately.

Uses

Uses:
Temporarily relieves the minor pains of muscles and joints associated with:
simple backache and arthritis

Dosage and administration

Dosage and administration:
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

Description

Ask a doctor before use if you have redness over the affected area.

Do not use: on wounds or damaged skin

Stop use and ask a doctor if excessive skin irritation occurs.

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

Question

Contact: smyou2@nate.com

PACKAGE LABEL. PRINCIPAL DISPLAY PANEL

BAROX

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52227-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	3 g in 120 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	82.2 g in 120 mL
ALCOHOL (UNII: 3K9958V90M)	18 g in 120 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	4.8 g in 120 mL
GERMANIUM DIOXIDE (UNII: 5O6CM4W76A)	0.96 g in 120 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.6 g in 120 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:52227-100-01	120 mL in 1 CARTON		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/01/2012	

Labeler - KTAIGA CO., LTD. (557819324)

Registrant - KTAIGA CO., LTD. (557819324)

Establishment

Name	Address	ID/FEI	Business Operations
KTAIGA CO., LTD.		557819324	manufacture(52227-100)

Revised: 8/2012 KTAIGA CO., LTD.