

**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.*

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**ACTIVE INGREDIENT**

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

**INACTIVE INGREDIENT**

Inactive Ingredients: Purified Water, Ethanol, Avocado Oil, Cetyl Palmitate, Polysorbate 80, Cetanol, Dimethyl Sulfone, Carbomer940, Aminomethyl Propanol, Methyl Parahydroxybenzoate, Chitosan, Emu oil, CI 42090

**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, rheumatalgia, 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
- Question Contact : jhs3840@naver.com

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

<p style="font-size: 2em; font-weight: bold;">BAROX<sup>®</sup></p>	<p style="font-size: 2em; font-weight: bold;">BAROX<sup>®</sup></p>	<p style="font-size: 2em; font-weight: bold;">BAROX<sup>®</sup></p>	<p style="font-size: 2em; font-weight: bold;">BAROX<sup>®</sup></p>
<p style="font-size: 1.5em; font-weight: bold;">BAROX<sup>®</sup></p>	<p style="font-size: 1.5em; font-weight: bold;">BAROX<sup>®</sup></p>	<p style="font-size: 1.5em; font-weight: bold;">BAROX<sup>®</sup></p>	<p style="font-size: 1.5em; font-weight: bold;">BAROX<sup>®</sup></p>
<p style="font-size: 1.2em;">Muscle &amp; Joint Pain Reliever</p>	<p style="font-size: 1.2em;">Muscle &amp; Joint Pain Reliever</p>	<p style="font-size: 1.2em;">Muscle &amp; Joint Pain Reliever</p>	<p style="font-size: 1.2em;">Muscle &amp; Joint Pain Reliever</p>
<p style="font-size: 0.8em;">Muscle Pain Arthralgia Neuralgia Rheumatalgia</p> 	<p style="font-size: 0.8em;">Muscle Pain Arthralgia Neuralgia Rheumatalgia</p> 	<p style="font-size: 0.8em;">Muscle Pain Arthralgia Neuralgia Rheumatalgia</p> 	<p style="font-size: 0.8em;">Muscle Pain Arthralgia Neuralgia Rheumatalgia</p> 
<p style="font-size: 1.2em; font-weight: bold;">100g</p>	<p style="font-size: 1.2em; font-weight: bold;">100g</p>	<p style="font-size: 1.2em; font-weight: bold;">100g</p>	<p style="font-size: 1.2em; font-weight: bold;">100g</p>

<p style="font-size: 1.2em; font-weight: bold;">BAROX S</p> <p>camphor (synthetic), methyl salicylate, menthol gel</p>			
<p style="font-size: 1.1em; font-weight: bold;">Product Information</p>			
<p style="font-size: 0.9em; font-weight: bold;">Product Type</p>	<p>HUMAN OTC DRUG</p>	<p style="font-size: 0.9em; font-weight: bold;">Item Code (Source)</p>	<p>NDC:55692-150</p>
<p style="font-size: 0.9em; font-weight: bold;">Route of Administration</p>	<p>TOPICAL</p>		
<p style="font-size: 1.1em; font-weight: bold;">Active Ingredient/Active Moiety</p>			
<p style="font-size: 0.9em; font-weight: bold;">Ingredient Name</p>		<p style="font-size: 0.9em; font-weight: bold;">Basis of Strength</p>	<p style="font-size: 0.9em; font-weight: bold;">Strength</p>
<p>CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)</p>		<p>CAMPHOR (SYNTHETIC)</p>	<p>5.90 g in 100 g</p>

<b>METHYL SALICYLATE</b> (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	4.60 g in 100 g
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.80 g in 100 g

<b>Inactive Ingredients</b>	
Ingredient Name	Strength
<b>Water</b> (UNII: 059QF0K00R)	
<b>AVOCADO OIL</b> (UNII: 6VNO72PFC1)	

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55692-150-01	100 g in 1 CARTON; Type 0: Not a Combination Product	10/01/2017	

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/01/2017	

**Labeler** - Barox Co., Ltd. (688380051)

**Registrant** - Barox Co., Ltd. (688380051)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Tai Guk Pharm. Co., Ltd_buyeo		689060246	manufacture(55692-150)

Revised: 11/2017

Barox Co., Ltd.