

## **BLUE ICE PAIN RELIEVING- menthol gel**

### **Genuine Drugs**

*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**

Menthol

Capsaicin

### **Purpose**

Pain Reliever

Pain Reliever

### **Uses**

For the temporary relief of minor aches and pains of muscles and joints associated with:

- arthritis • simple backache • strains
- bruises • sprains

### **Warnings**

#### **For external use only**

#### **Do not use**

- with other topical pain relievers
- with heating pads or heating devices

#### **When using this product**

- avoid contact with the eyes
- use only as directed
- do not apply to wounds or damaged skin
- do not bandage tightly

#### **Stop use and ask a doctor if**

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days
- redness or irritation develops

#### **If pregnant or breast-feeding,**

ask a health professional before use

#### **Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away.

### **Directions**

- clean affected area before applying product
- adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily
- children under 2 years of age: ask a doctor

### Other information

- store at room temperature
- keep lid tightly closed
- do not use, pour, spill or store near heat or open flame

### Inactive ingredients

ammonium hydroxide, carbomer, cupric sulfate, FD&C blue no. 1, isopropyl alcohol, magnesium sulfate, sodium hydroxide, thymol, water

### Package label



**BLUE ICE PAIN RELIEVING**  
 menthol gel

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69666-368
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	.05 g in 1 g
capsaicin (UNII: S07O44R1ZM) (capsaicin - UNII:S07O44R1ZM)	capsaicin	.00025 g in 1 g

**Inactive Ingredients**

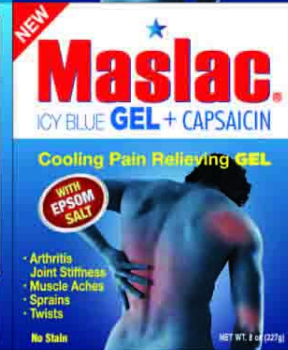
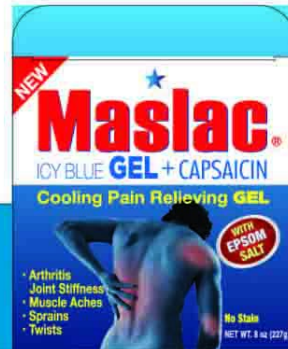
<b>Ingredient Name</b>	<b>Strength</b>
AMMONIA (UNII: 5138Q19F1X)	
CUPRIC SULFATE (UNII: LRX7AJ16DT)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MAGNESIUM SULFATE (UNII: DE08037SAB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
THYMOL (UNII: 3J50XA376E)	
WATER (UNII: 059QF0KO0R)	

**Product Characteristics**

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:69666-368-08	1 in 1 BOX		
1		227 g in 1 JAR		



## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/17/2015	

**Labeler** - Genuine Drugs (079610378)

Revised: 3/2015

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