AMORAY ANALGESIC GEL- menthol gel
MY IMPORTS USA LLC

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.

AMORAY Ice Gel

Active Ingredients

Menthol 1.25 %

Camphor 0.5%

Purpose

Topical Analgesic

***Uses*:**

- for temporary relief of minor aches and pains in muscles and joints associated with:
- simple backaches,
- strains
- sprains
- sports injuries
- arthritis
- bruises

Warnings

FOR EXTERNAL USE ONLY

Do not use:

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

When using this product

- do not use in or near eyes
- 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 breastfeeding

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

Inactive Ingredients

Carbomer, FD&C Blue No.1, Methyl Paraben Sodium, Methyl Salicylate, Propylene Glycol, Propyl Paraben Sodium, Sodium hydroxide, Water

AMORAY ANALGESIC GEL

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51628-3021
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1.25 g in 100 g
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	0.5 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
METHYLPARABEN SODIUM (UNII: CR6K9C2NHK)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PROPYLPARABEN SODIUM (UNII: 625NNB0G9N)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

METHYL SALICYLATE (UNII: LAV5U5022Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51628-3021-2	227 g in 1 JAR; Type 0: Not a Combination Product	04/08/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/08/2019	

Labeler - MY IMPORTS USA LLC (195767988)

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