# BIOCOOL FOCUS ON- menthol gel JJindustry.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: Menthol 3.5%

#### INACTIVE INGREDIENT

Inactive ingredients:

Purified water, isopropyl alcohol, glycerin, phytoncide, peppermint oil, lavender oil, eucalyptus oil, licorice extract, methyl sulfonyl methane,

carbomer, sodium hydroxide, PEG-60 hydrogenated castor oil, methyl parahydroxybenzoate, FD & C

#### **PURPOSE**

Purpose: Topical Analgesic

#### **WARNINGS**

Warnings:

- Do not use the product if there are any abnormalities such as red spots, swelling or itching.
- Do not use the product in the areas with abnormalities such as scratches, eczema and dermatitis.
- Do not use the product near the eyes. In case of contact with eyes, wash immediately with water.
- Keep out of reach of children.
- After use, close the cap tightly and keep it at room temperature.

#### KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children

#### Usages

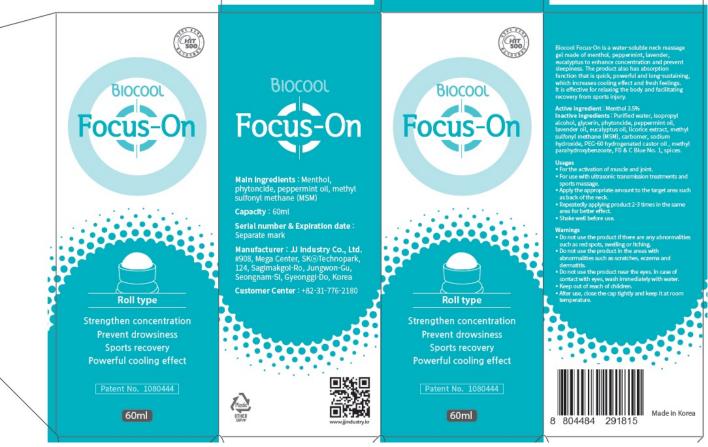
Usages: For the activation of muscle and joint. For use with ultrasonic transmission treatments and sports massage. Apply appropriate amount onto affected area and rub until fully absorbed. It's more effective when applied 2~3 times repeatedly.

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#### PACKAGE LABEL.PRINCIPAL DISPLAY PANEL





### **BIOCOOL FOCUS ON**

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70612-030
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Menthol (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	Menthol	2.1 g in 60 mL	

Inactive Ingredients		
Ingredient Name	Strength	
Water (UNII: 059QF0KO0R)		
Glycerin (UNII: PDC6A3C0OX)		

]	Packaging			
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70612-030- 02	1 in 1 CARTON	10/01/2018	
1	NDC:70612-030- 01	60 mL in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	10/01/2018		

## Labeler - JJindustry.Co.Ltd (689605084)

## Registrant - JJindustry.Co.Ltd (689605084)

Establishment			
Name	Address	ID/FEI	Business Operations
JJindustry.Co.Ltd		689605084	manufacture (70612-030)

Revised: 11/2018 JJindustry.Co.Ltd