

**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**

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**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:706 12-0 30
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

#	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