NUDROXICIN PAIN RELIEF ROLL-ON- methyl salicylate, menthol, capsaicin liquid
NuCare Pharmaceuticals Inc

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.

NuDroxicin pain relief Roll-On

DRUG FACTS:

ACTIVE INGREDIENTS:

Methyl Salicylate 25.00%
Menthol 6.00%
Capsaicin 0.025%

Topical Analgesic

USES:

Use for the temporary relief of minor aches and muscle pains associated with arthritis, simple backache, strains, muscle soreness and stiffness.

WARNINGS:

- For external use only. Use only as directed. Avoid contact with eyes and mucous membranes or genitals.
- Do not cover or tightly bandage area.
- on wounds or damaged skin.
- Do not use with heating pad.

Do not use

On cuts or infected skin, on children less than 12 years old in large amount.

STOP USE AND ASK A PHYSICIAN:

For severe undiagnosed pain. If pain worsens or persist for more than 7 days. If itching or rash occurs.

Keep out of reach of children.

Consult physician for children under 12.

DIRECTIONS:

Shake before each use. Prior to first use rub small amount to check for sensitivity. Apply product directly to affected area. Dry before contact with clothes or bedding to avoid staining. Wash hands after use. Product may be used as necessary, but should not be used more than four times per day.

STORE BELOW (90°F/32°C)

OTHER INGREDIENTS:

Aqua (Deionized Water), Arnica Montana Flower Extract, Beeswax, Boswellia Serrata Extract,

Carbomer, Cetearyl Olivate, Ethylhexylglycerin, Glyceryl Stearate, Ilex Paraguayensis (Yerba Mate') Extract, Magnesium Sulfate, Methylsulfonylmethane (MSM), Phenoxyethanol, Polysorbate-20, SD-Alcohol 40B, Sorbitan Olivate, Triethanolamine

Package Labeling:

NUDROXICIN PAIN RELIEF ROLL-ON

methyl salicylate, menthol, capsaicin liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70859-028
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	250 mg in 1 mL
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	60 mg in 1 mL
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.25 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70859-028-03	1 in 1 CARTON	02/06/2018	
1		90 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	11/18/2017	

Labeler - NuCare Pharmaceuticals Inc (010632300)

Revised: 2/2018 NuCare Pharmaceuticals Inc