

ZEROMA7- peppermint oil, camphor oil gel

Ingenue Care 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.

Zeroma7

Uses

Uses Aroma therapy blend essential oil for temporary relieves minor aches, pains of muscles and joints associated with:

Arthritis Simple backache Strains Bruises Sprains

Warnings

For external use only

Do not use on wounds or damaged skin with a heating pad

if you are allergic to any ingredients of this product

with other external analgesic products

When using this product

Use only as directed

avoid contact with eyes, mucous membranes or rashes

do not bandage tightly

Stop use and ask a doctor if

rash, itching, or excessive skin irritation develops

conditions worsen

symptoms persist for more than 7 days

symptoms clear up and occur again within a few days

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

If pregnant or breast-feeding, ask a health professional before use

Active Ingredients

Peppermint Oil 8% ----- Topical Analgesic

Camphor Oil 8% ----- Topical Analgesic

Purpose

Topical Analgesic

Directions

Adults and children 12 years of age and over:

Clean and dry affected area

Remove patch from film

Apply to affected area no more than 3 to 4 times daily for 7 days

Remove patch from skin after at most 8 hours' application

Children undress 12 years of age: consult a doctor

Inactive Ingredients

Gaultheria Procumbens (Wintergreen) Oil, Rosmarinus Officinalis (Rosemary) Oil, Citrus Paradisi (Grapefruit) Oil, Heterotheca Inuloides (Arnica Herbal) Oil, Aloe Vera Leaf Extract, Witch Hazel, Olive Oil, Carbomer, Water, Stearic Acid, Propylene Glycol, Isopropyl Palmitate, Cetyl Alcohol, Glycerol Stearate, Lanolin, Polymethoxy Bicyclic Oxazolidine, Mineral Oil & Lanolin Alcohol, Allantoin, Tocopherol Acetate, Aloe Vera Gel, Methyl Paraben, Urea, Potassium Hydroxide, Chloroxylenol, Propyl Paraben, Sodium Hydroxide.

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이 문구는 FDA규제상 문제가 될 수 있습니다. 삭제해주세요.

보통 3 fl. oz (90 mL) 이렇게 표기합니다.

ZEROMA7

peppermint oil, camphor oil gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72589-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	6.8 g in 85 g
PEPPERMINT OIL (UNII: AV092KU4JH) (PEPPERMINT - UNII:V95R5KMY2B)	PEPPERMINT OIL	6.8 g in 85 g

Inactive Ingredients

Ingredient Name	Strength
GAULTHERIA PROCUMBENS LEAF (UNII: 2125M16OWN)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72589-100-01	85 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/08/2018	

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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/08/2018	

Registrant - Ingenue Care Inc (111556736)**Establishment**

Name	Address	ID/FEI	Business Operations
Ingenue Care Inc		111556736	manufacture(72589-100)

Revised: 10/2018

Ingenue Care Inc