WARMING EPSOM RUB- menthol granule, for solution OLD EAST MAIN CO

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.

Permeating Heat Sports Rub 672.000/672AA

active ingredients

Menthol (1.25 w/w)

Purpose

Topical Analgesic

Use

for the temporry relief of minor aches and pains of muscle joints associated with simple backache, arthritis, strains, bruises, and sprains

Warnings

For external use only

Flammable

• keep away from fire or flame, heat, spark, electrical

When using this product

- avoid contact with the eyes
- do not apply to wounds or damaged skin
- do not bandage tightly

Stop use and ask a doctor if

condition worsens, or if symptoms persist for more then 7 days or 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 right way.

Directions

adults and children 2 years of age and older - apply to affected area not more than 3 to 4 times daily

children under 2 years of age - consult a doctor

Directions for Use as Relaxing Soak Solution:

For external use only. Pour Liberally into warm water no more than 4 times daily

Caution

If prompt relief is not obtained or there is evidence of infection, discontinue use and consult your physician. Individuals with diabetes should not use for hot or warm soaks unless advised by a physician.

Other information

- does not contain, nor is intended as a substitute for grain or ethyl alcohol
- will produce serious gastric distributances if taken internally
- fumes can be acutely irritating to respiratory system. Avoid inhaling this product

inactive ingredients

water, isopropyl alcohol, Capsicum frutescens fruit extract, methyl salicylate, magnesium sulfate, red 40

FOR EXTERNAL USE AS A SOAK: POUR LIBERALLY INTO WARM WATER NO MORE THAN 4 TIMES DAILY.

CAUTION: IF PROMPT RELIEF IS NOT OBTAINED OR THERE IS EVIDENCE OF INFECTION, DISCONTINUE USE AND CONSULT YOUR PHYSICIAN. HOT OR WARM SOAKS SHOULD NOT BE USED BY INDIVIDUALS WITH DIABETES EXCEPT ON THE ADVICE OF A PHYSICIAN. KEEP OUT OF REACH OF CHILDREN.

DISTRIBUTED BY OLD EAST MAIN

100 MISSION RIDGE

GOODLETTSVILLE, TN 37072

672.000/672AA

PRINCIPAL DISPLAY PANEL

Rexall

Permeating Heat Sports Rub

PAIN RELIEVING & SOAKING SOLUTION

Penetrating pain relief

Temporarily relieves pains associated with:

- Arthritis
- Minor aches
- Sprains
- Tired feet

16 FL OZ (1 PT) 473 mL



WARMING EPSOM RUB

menthol granule, for solution

Product Information

Product Type

HUMAN OTC DRUG

Route of Administration

TOPICAL

Active Ingredient/Active Moiety
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Ingredient Name		Basis of Strength	Strength
	MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	12.5 mg in 1 mL

Inactive Ingredients				
Ingredient Name	Strength			
water (UNII: 059QF0KO0R)				
ISOPROPYL ALCOHOL (UNII: ND2M416302)				
CAPSICUM (UNII: 00UK7646FG)				
METHYL SALICYLATE (UNII: LAV5U5022Y)				

FD&C RED NO. 40 (UNII: WZB9127XOA)

MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)

ı	P	Packaging			
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:55910- 672-43	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/05/2015	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/05/2015	

Labeler - OLD EAST MAIN CO (068331990)

Revised: 2/2023 OLD EAST MAIN CO