THRITEX- menthol patch
Binger Consulting Corporation

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.

Thritex

Drug Facts

Active ingredient

Menthol 5.00%

Purpose

Analgesic/Counterirritant

Keep out of reach of children. Consult physician for children under 12.

Uses

• temporary relief of minor aches and muscle pains associated with arthritis, simple backache, strains, muscle soreness and stiffness

Warnings

For external use only

Do not use

• on wounds or damaged skin

• if you are allergic to Menthol

When using this product

• do not cover with bandage

• use only as directed

• avoid contact with eyes and mucous membranes

Stop use and ask a doctor if

• conditions worsen, symptoms persist for more than 7 days or clear up and occur again within a few days

• rash, itching or excessive skin irritation occurs

Directions adults and children 12 years and over apply to affected area; change patch

1 to 2 times daily

How to apply

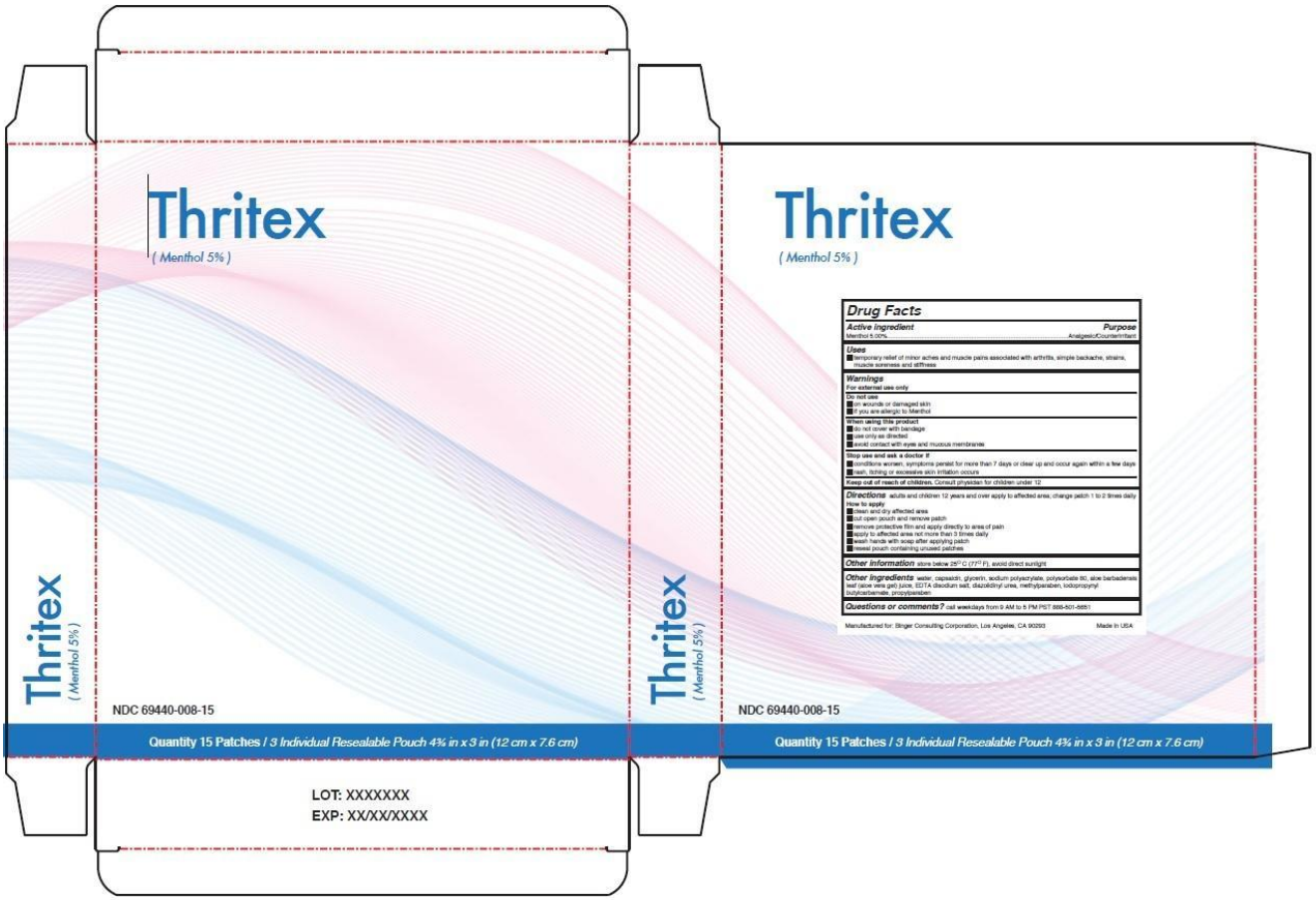
- clean and dry affected area
- cut open pouch and remove patch
- remove protective film and apply directly to area of pain
- apply to affected area not more than 3 times daily
- wash hands with soap after applying patch
- reseal pouch containing unused patches.

Other ingredients water, capsaicin, glycerin, sodium polyacrylate, polysorbate 80, aloe barbadensis leaf (aloe vera leaf) juice, EDTA disodium salt, diazolidinyl urea, methylparaben, iodopropynyl butylcarbamate, propylparaben

Questions or comments? call weekdays from 9 AM to 5 PM PST 888-501-5651

Other information store below 25°C (77°F), avoid direct sunlight

Packaging



THRITEX
menthol patch

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69440-008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CAPSAICIN (UNII: S07O44R1ZM)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69440-008-15	15 in 1 BOX	01/01/2015	
1		100 g in 1 PATCH; 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	01/01/2015	

Labeler - Binger Consulting Corporation (079635976)

Establishment

Name	Address	ID/FEI	Business Operations
Active Intelligence, LLC		080416593	manufacture(69440-008)