DOCTORRELIEF- menthol patch Biotanico 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.

DoctorRelief

Actives

Active ingredients Purpose

Menthol 50 mg patch......Topical analagesic

Topical analgesic

Indication

Uses

Temporary relief minor aches and pains of muscles and joints associated with:

■ Arthritis ■ Bruises ■ Simple backache ■ Strains ■ Sprains

Warnings

For external use only

When using this product:

- Use only as directed
- Avoid contact with eyes ,mucous membranes or rashes
- Do not apply to broken, wounded or damaged skin
- Do not bandage or cover with any type of wrap except clothing
- Do not use with a heating pad or apply external heat
- Discontinue use at least 1 hour before a bath or shower and do not use immediately after a bath or shower

Questons

Stop use and ask a doctor if

- Rash, itching or excessive skin irritation develops
- Condition worsens or does not improve after regular use
- Symptoms persist for more than 7 days or clear up and occur again within a few days

OTC-Keep out of reach of children

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center immediately

Dosages

Directions

Adult and children 12 years of age and over

- Clean and dry affected area
- Open pouch and remove patch. If desired, cut patch to size
- Peel off protective backing and apply sticky side to affected area

- Apply to affected area not more than 3 times daily
- Wash hands with soap after applying patch Children under 12 years of age
- Consult a doctor

Warning and Precautions

- Do not apply on Ulcerative or suppurative skin area
- Not be used by during pregnancy
- This product may cause allergic reaction in some individuals.

Ask Doctor

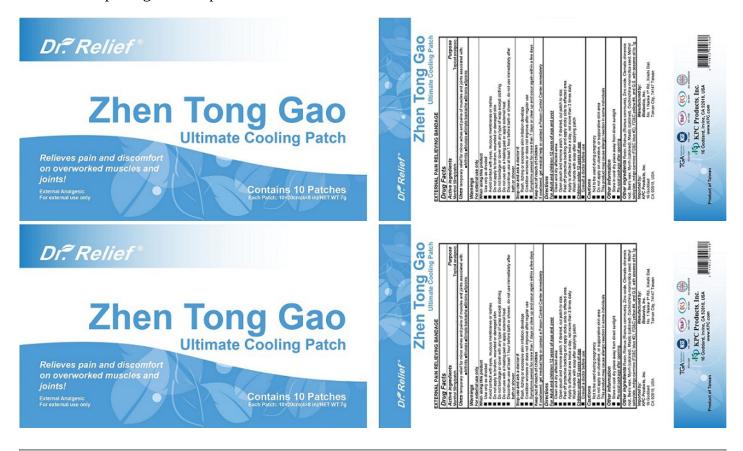
- Ask a doctor if symptoms persist for more than 7 days or clear up and occur again within a few days
- Rash, itching, execessive skin irritation develop
- condition worsen or dose not improve after regular use

Inactives

Rosin,Rinus(Ricinus communis),zinc oxide,Clematis chinensis root,Bee'wax,Myrrh(calcined),Mastic(calcined),Cochinchina momordica seed, Methyl salicylate,Indigo carmine(F,D&C# Blue),F,D&C #Yellow and Q.S with sesame oil to 1g

Storage and handling section

- Store in cool dry place from directly sunlight
- Re-seal package arter open



menthol patch

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:57842-7734

Route of Administration TOPICAL

Active Ingredient/Active Moiety

	Ingredient Name	Basis of Strength	Strength
ı	Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Me ntho l	50 mg

Inactive Ingredients			
Ingredient Name	Strength		
ROSIN (UNII: 88S87KL877)			
RICINUS COMMUNIS WHOLE (UNII: Q94QWM85RF)			
ZINC OXIDE (UNII: SOI2LOH54Z)			
CLEMATIS CHINENSIS ROOT (UNII: 8Z18N528CU)			
YELLOW WAX (UNII: 2ZA36H0S2V)			
MYRRH (UNII: JC71GJ1F3L)			
PISTACIA LENTISCUS RESIN (UNII: 7446 H20 2QW)			
MOMORDICA COCHINCHINENSIS SEED (UNII: 2T87O1UPVD)			
METHYL SALICYLATE (UNII: LAV5U5022Y)			
INDIGOTINDISULFONATE SODIUM (UNII: D3741U8K7L)			
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)			
SESAME OIL (UNII: QX10 HYY4QV)			
QS-21 (UNII: 61H83WZX3U)			

Product Characteristics			
Color	yellow (FD&C YELLOW NO. 5), blue (FD&C BLUE NO. 2), red (FD&C RED NO. 40)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
l	# Item Code Package Description		Marketing Start Date	Marketing End Date
l	1 NDC:57842-7734-1	10 in 1 CARTON; Type 0: Not a Combination Product	02/02/2018	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	0 1/0 3/20 18	

Labeler - Biotanico Inc. (658835665)

Registrant - Biotanico Inc. (658835665)

Establishment				
Name	Address	ID/FEI	Business Operations	
Biotanico Inc.		658835665	manufacture (578 42-7734)	

Revised: 3/2018 Biotanico Inc.