

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 analgesic

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

Questions

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,excessive 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 Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57842-7734
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	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: 7446H202QW)	
MOMORDICA COCHINCHINENSIS SEED (UNII: 2T87O1UPVD)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
INDIGOTINDISULFONATE SODIUM (UNII: D3741U8K7L)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
SESAME OIL (UNII: QX10HYY4QV)	
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

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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	01/03/2018	

Labeler - Biotanico Inc. (658835665)

Registrant - Biotanico Inc. (658835665)

Establishment

Name	Address	ID/FEI	Business Operations
Biotanico Inc.		658835665	manufacture(57842-7734)

Revised: 3/2018

Biotanico Inc.