# DENTAL C-PATCH- menthol, camphor patch NeoBiotech Global 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.

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#### **Dental C-Patch**

# **Active ingredients**

Camphor (0.5%)

Menthol (2.5%)

### **Purpose**

External analgesic

#### Uses

temporarily relieves symptoms of

- discomfort after dental procedure
- inflammation
- minor irritation
- swelling

## Warnings

For external use only

When using this product

Use only as directed.

- Do not bandage tightly or use with heating pad
- Avoid contact with eyes and mucus membranes
- Do not appy wounds or broken skin
- Do not apply to large areas of the body
- In case of deep or puncture wounds, animal bites or serious burns, consult a doctor

Stop use and ask a doctor if

- condition worsen
- irritation develops
- symptoms persist for more than 7 days or recurs within 1 day of discontinuation
- do not use for more than 7 days

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

Keep out of reach of children. If swallowd, contact a Poison Control Center or get medical help immediatel

#### **Directions**

Adults and children over 12 years:

- remove film from patch
- carefully apply the patch to the affected skin over the area of ental procedure
- press patch onto skin firmly
- patch can remain on the skin for up to 8 hours
- may repeat as necessary up to 3 times per day

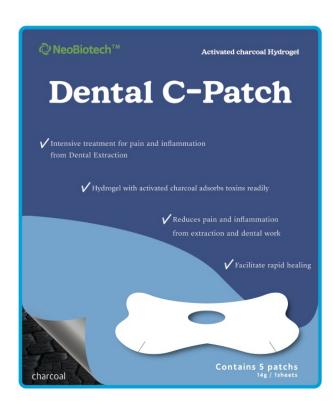
### **Inactive ingredients**

Charcoal, gelatin, Aluminum glycinate, Ethylenediaminetetraacetic acid, disodium slat, eucalyptus oil, glycerin, polyvlnyl alcohol, partially neutralized polyacrytate, pured wter, salt, sorbitol, tartaric acid

#### Keep out of reach of children

Keep out of reach of children. If swallowed, contact a Poison Control Center or get medical help immediately

#### **Dental C-Patch**





#### DENTAL C-PATCH

menthol, camphor patch

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70236-104	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	0.07 g in 14 g	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.35 g in 14 g	

Inactive Ingredients			
Ingredient Name	Strength		
EDETIC ACID (UNII: 9G34HU7RV0)			
ACTIVATED CHARCO AL (UNII: 2P3VWU3H10)			
DIHYDROXYALUMINUM AMINO ACETATE ANHYDROUS (UNII: 1K713C615K)			
SORBITOL (UNII: 506T60A25R)			
TARTARIC ACID (UNII: W4888I119H)			
GLYCERIN (UNII: PDC6A3C0OX)			
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)			
EUCALYPTUS OIL (UNII: 2R04ONI662)			
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)			
WATER (UNII: 059QF0KO0R)			
SODIUM CHLORIDE (UNII: 451W47IQ8X)			

Packaging				
7	# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
:	NDC:70236-104-02	5 in 1 POUCH	02/10/2018	
:	NDC:70236-104-01	14 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	02/10/2018		

# Labeler - NeoBiotech Global Corporation (080020820)

# **Registrant** - NeoBiotech Global Corporation (080020820)

Establishment				
Name	Address	ID/FEI	Business Operations	
NeoBiotech Global Corporation		080020820	manufacture(70236-104)	