ALL NATURAL EYE PATCH- menthol patch Tianjin Oculax Biotech 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.

Tianjin Oculax Biotech Inc

ACTIVE INGREDIENT

Menthol 2.5%

PURPOSE

Menthol External Analgesic

USES

For the temporary relief of minor aches and pains of the eyes.

Warnings

For External Use only.

Do not use

on wounds.
on irritated or damaged skin.
if the appearance of this product has changed.
if you are hypersensitive to this product.
otherwise than as directed.

Ask a Doctor or Pharmacist Before Use If you are

pregnant. taking other medications.

When using this product

avoid contact with the eye or mucous membranes. supervise use by children. use caution if prone to allergic reactions.

Stop Use and Ask a Doctor If

condition worsens.
symptoms persist for more than 7 days.
symptoms clear up and occur again within a few days.
excessive irritation of the skin develops.
redness is present.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Adults and children 6 years of age and older: Apply patches to areas as diagram shown. Remove after 8 hours. Children 2 to 6 years of age and adults with compromised health: Use only under the guidance of a doctor. Children under 2 years of age: Do not use, consult a doctor. Refer to the above warnings: use otherwise than as directed.

Other Information

Use immediately after individual package is opened. Store below $35 \, \mathbb{I}$ (95 \mathbb{I}) in a dry area.

Inactive Ingredients

GLYCERIN, LIGUSTICUM WALLICHII ROOT, SALVIA MILTIORRHIZA ROOT, CHRYSANTHEMUM INDICUM FLOWER, LAVANDULA ANGUSTIFOLIA FLOWER, ANGELICA ARCHANGELICA ROOT

Questions or Comments?

3T Herbtech Inc. (800)668-8922 mfg3t@3t-herb.com

Manufactured by Tianjin Oculax Biotech Inc 6 Ziyuan Road, B201 Huayuan Domain District Tianjin 300131, China

Distributed by

3T Herbtech Inc. 1720 S. San Gabriel Blvd, Suite 111 San Gabriel, CA 91776 USA

Drug Facts



ALL NATURAL EYE PATCH

menthol patch

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72455-001	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2.5 mg in 100 mg		

Inactive Ingredients

Ingredient Name	Strength	
GLYCERIN (UNII: PDC6A3C0OX)		
LIGUSTICUM WALLICHII ROOT (UNII: R8 1AD159 QS)		
SALVIA MILTIORRHIZA ROOT (UNII: 1693AM5SBN)		
CHRYSANTHEMUM INDICUM FLO WER (UNII: 16 O ER6 U 0 4 L)		
LAVANDULA ANGUSTIFOLIA FLOWER (UNII: 19 AH1RAF4M)		
ANGELICA ARCHANGELICA ROOT (UNII: DTN0 1M69 SN)		

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72455-001-20	120 in 1 BOX	07/24/2018	
1	NDC:72455-001-10	60 in 1 BOX		
1	NDC:72455-001-05	30 in 1 BOX		
1		24 mg 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	07/24/2018		

Labeler - Tianjin Oculax Biotech Inc (542949666)

Registrant - Tianjin Oculax Biotech Inc (542949666)

Establishment				
Name	Address	ID/FEI	Business Operations	
Tianjin Oculax Biotech Inc		542949666	manufacture(72455-001)	

Revised: 9/2018 Tianjin Oculax Biotech Inc