

MENTHOL- menthol, unspecified form patch
Unexo Life Sciences Private Limited

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.

Menthol 7.5% Patch

Drug Facts

Active Ingredient

Menthol 7.5%

Topical analgesic

Uses

Temporarily relieves minor aches and pains of muscles and joints due to:

- arthritis
- simple backache
- strains
- sprains
- bruises

Warnings

For external use only

Ask a doctor before use if you have

- Sensitive skin

When using this product

- Use only as directed
- Avoid contact with eyes and mucous membranes
- Do not apply to wounds or damaged skin
- Do not bandage tightly or use a heating pad

Stop use and ask a doctor if

- Excessive irritation or redness is present
- Condition worsens
- Pain persists for more than 7 days
- Symptom clear up and occur again within a few days

Do not use

- With other creams, ointments, sprays, liniments, or other topical products containing menthol.

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

Directions

Adults and children over 12 years: Gently fold patch in half and remove one side of backing. Apply exposed adhesive to the site of pain. Remove remaining film from the other side and finish applying to skin. Use on affected areas for up to 12 hours. Children 12 years of age or younger: Consult a doctor

Other Information

Store in a cool & dry place. Protect from excessive moisture. Do not refrigerate or freeze.

Inactive Ingredients

Glyceryl Hydrogenated Rosinate, Mineral Oil, Styrene/Isoprene Copolymer

Questions or Comments

Call +91 9212228401

Manufactured By:

UNEXO LIFE SCIENCES PVT. LTD.
B-16. Sector 4, Bawana Industrial Area,
Delhi - 110039 (INDIA)

PRINCIPAL DISPLAY PANEL - 5 Patch Pouch Box

NDC: 71391-128-05

MENTHOL 7.5% PATCH

COOLING PAIN RELIEF PATCH
WITH 7.5% NATURAL MENTHOL

Backaches, Sore Muscles & Joint Pain
Fast Acting Cooling Relief

5 PATCHES

5.51" X 3.94"

(14cm X 10cm)

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Purpose

Menthol 7.5%Topical analgesic

Uses Temporarily relieves minor aches and pains of muscles and joints due to:
• arthritis • simple backache • strains • sprains • bruises

Warnings

For external use only.

Ask a doctor before use if you have: Sensitive Skin

When using this product • use only as directed • avoid contact with the eyes and mucous membranes • do not apply to wounds or damaged skin • Do not bandage tightly or use a heating pad

Stop use and ask a doctor if

- excessive redness or irritation is present
- condition worsens
- pain persists for more than 7 days
- symptoms clear up and occur again within a few days

Do not use: with any other creams, ointments, sprays, liniments, or other topical products containing menthol.

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

Directions

Adults and children 12 years and over: • gently fold patch in half and remove one side of backing. Apply exposed adhesive to the site of pain. • remove remaining film from the other side and finish applying to skin. • use on affected areas for up to 12 hours
Children 12 years of younger: ask a doctor

Other information: Store in a cool & dry place. Protect from excessive moisture. Do not refrigerate or freeze.

Inactive ingredients

Glyceryl Hydrogenated Rosinate, Mineral Oil, Styrene/Isoprene Copolymer.

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UNEXO LIFE SCIENCES PVT. LTD.
B-16, Sector 4, Bawana Industrial Area,
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Phone: +91 9212228401
Email: info@unexopharma.com

Made in India
NC/DL-378-A&U

NDC: 71391-128-05

MENTHOL

menthol, unspecified form patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71391-128
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	105 mg

Inactive Ingredients

Ingredient Name	Strength
GLYCEROL ESTER OF HYDROGENATED ROSIN (UNII: XH62RP786N)	
Mineral Oil (UNII: T5L8T28FGP)	
STYRENE/ISOPRENE/STYRENE BLOCK COPOLYMER (UNII: K7S96QM8DV)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71391-128-01	1 in 1 POUCH; Type 0: Not a Combination Product	11/15/2022	
2	NDC:71391-128-05	5 in 1 BOX	11/15/2022	
2	NDC:71391-128-01	1 in 1 POUCH; 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	11/15/2022	

Labeler - Unexo Life Sciences Private Limited (872260479)**Establishment**

Name	Address	ID/FEI	Business Operations
Unexo Life Sciences Private Limited		872260479	MANUFACTURE(71391-128)

Revised: 11/2022

Unexo Life Sciences Private Limited