

TEMPO COOL- menthol patch

The Egyptian Saudi Co. For Medical Manufacturing (Masco-Mid) S.A.E

TempoCOOL

Purpose Section

- Children suffering from high temperature or fever
- Adults suffering from headache and migraine

Warnings

- FOR EXTERNAL USE ONLY
- Tempo cool has no side effects and used safely with all medications.
- Avoid contacts with eyes.
- Do not bandage tightly.
- Do not apply to wound or damaged skin

Dosage

- One sheet for 8 hours.

Directions

- Peel off the transparent layer, attach Sheet to the forehead area or back of the neck.

Stop use and ask doctor

- If condition worsens

Storage

- Store in a cool dry place.
- Avoid direct sunlight.

KEEP OUT OF REACH OF CHILDREN

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

Active Ingredient section

Menthol 0.3 %

Camphor. 1%

Inactive Ingredient section

Glycerin ,Sodium polyacrylate , Anhydrous citric acid ,Tartaric acid ,Poly sorbate -80

(tween 80) ,
 EDETA ,Water.

Carton



TEMPO COOL

menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72602-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	3 mg in 1 g
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	1 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05115JN12J)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
TARTARIC ACID (UNII: W4888119H)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
CARBOXYMETHYLCELLULOSE SODIUM (0.9 CARBOXYMETHYL SUBSTITUTION PER SACCHARIDE; 600 MPA.S AT 2%) (UNII: ZY4732LP1O)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POLYACRYLIC ACID (800000 MW) (UNII: D0I6NSZ87U)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72602-003-01	3 g in 1 PATCH; Type 0: Not a Combination Product	09/21/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	09/20/2018	

Labeler - The Egyptian Saudi Co. For Medical Manufacturing (Masco-Mid) S.A.E (850486280)

Registrant - The Egyptian Saudi Co. For Medical Manufacturing (Masco-Mid) S.A.E (850486280)

Establishment

Name	Address	ID/FEI	Business Operations
The Egyptian Saudi Co. For Medical Manufacturing (Masco-Mid) S.A.E		850486280	manufacture(72602-003)

Revised: 10/2023

The Egyptian Saudi Co. For Medical Manufacturing (Masco-Mid) S.A.E