

ASPERCREME WARMING- capsaicin patch
Chattem, 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.

Aspercreme Warming Patch

ASPERCREME WARMING PAIN RELIEF PATCH

Drug Facts

Active ingredient

Capsaicin 0.025%

Purpose

Topical analgesic

Uses

temporarily relieves minor pain associated with:

- arthritis ■ simple backache ■ muscle strains ■ sprains ■ bruises ■ cramps

Warnings

For external use only

When using this product

- read inside of carton before using
- use only as directed. Read and follow all directions and warnings on this carton
- avoid contact with the eyes and mucous membranes
- rare cases of serious burns have been reported with products of this type
- do not bandage tightly or apply local heat (such as heating pads)
- do not apply to wounds or damaged, broken or irritated skin
- do not use at the same time as other topical analgesics
- discontinue use at least 1 hour before a bath or shower
- a transient burning sensation may occur upon application but generally disappears in several days
- if severe burning occurs, discontinue use immediately and read inside carton for important information
- dispose of used patch in manner that always keeps product away from children and pets. Used patches still contain the drug product that can produce serious adverse effects if a child or pet chews or ingests this patch.

Stop use and ask a doctor if

- condition worsens

- redness is present
- irritation develops
- symptoms persist for more than 7 days or clear up and occur again within a few days
- you experience signs of skin injury, such as pain, swelling, or blistering where the product was applied

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children and pets.

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

Directions

adults 18 years of age and older:

- clean and dry affected area
- remove backing from patch by firmly grasping both ends and gently pulling until backing separates in middle
- carefully remove smaller portion of backing from patch and apply exposed portion of patch to affected area
- once exposed portion of patch is positioned, carefully remove remaining backing to completely apply patch to affected area
- apply one patch to affected area for up to 8 hours, repeat as necessary, but no more than 3 times a day
- **AFTER APPLYING, WASH HANDS WITH SOAP AND WATER**

children under 18 years of age: ask a doctor

Inactive ingredients

aluminum hydroxide, benzyl alcohol, cellulose gum, disodium EDTA, glycerin, isopropyl myristate, methyl acrylate/2-ethylhexyl acrylate copolymer, nonoxynol-30, polyacrylic acid, polysorbate 80, sodium polyacrylate, starch/acrylic acid graft copolymer sodium salt, talc, tartaric acid, titanium dioxide, tocopherol, water

Keep carton as it contains important information.

PRINCIPAL DISPLAY PANEL

Aspercreme

WARMING

PAIN RELIEF PATCH

Contains 5 patches in 1 resealable pouch

0.025% Capsaicin



ASPERCREME WARMING

capsaicin patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-1920
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	1.506 mg

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	

NONOXYNOL-30 (UNII: JJX07DG188)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
TALC (UNII: 7SEV7J4R1U)	
TARTARIC ACID (UNII: W4888119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
.ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41167-1920-1	1 in 1 CARTON	01/02/2019	
1		5 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	01/02/2019	

Labeler - Chattem, Inc. (003336013)