

**MENTHOL, CAPSAICIN- vitacin patch**  
**MAS Management Group 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.*

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**ACTIVE INGREDIENTS**

Menthol 5%

**PURPOSE**

External Analgesic

**USES**

For the temporary relief of minor aches and pains of the muscles and joints associated with simple backache, arthritis, sprains, bruises and strains.

**WARNINGS**

- For external use only.
- Use only as directed.
- Avoid contact with eyes and mucous membranes.
- Do not cover with bandage.
- Do not use on wounds or damaged skin.
- Do not use in combination with any other external analgesic products.
- Do not use on irritated or broken skin, or use in combination with any bandage, wrap, stocking or similar device or garment.

**Keep out of reach of children**

Consult physician for children under 12.

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

**Pregnancy or Breast Feeding**

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

**DIRECTIONS**

- Adults and children 12 years and over apply to affected area; change patch 1 to 2 times daily.
- Children under 12years, consult physician before use
- Clean and dry affected area
- Remove protective film and apply directly to area of pain
- Apply to affected area not more than 3 times daily
- Wash hands with soap after applying patch
- Reseal pouch containing unused patches

**INACTIVE INGREDIENTS**

WATER, GLYCERINE, SODIUM POLYACRYLATE, POLYSORBATE 80, ALOE BARBADESIS LEAF (ALOE VERA)

GEL) JUICE, EDTA DISODIUM SALT, DIAZOLIDINYL UREA, METHYLPARABEN, LODOPROYNYL BUTYLCABAMATE, PROPYLPARABEN.

**Storage and Handling**

Store in dry area between 59-79 F(15-26 C)

**Questions or Comments**

Please call (800) 768-3518

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Children under 12years, consult physician before use.

**VitaCin Patch**



vitacin patch

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69677-011
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.375 mg in 1 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	50 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
EDETATE DISODIUM (UNII: 7FLD91C86K)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69677-011-15	15 in 1 BOX	09/01/2016	
1		8 g in 1 PATCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/01/2016	

**Labeler** - MAS Management Group Inc. (079363782)

### Establishment

Name	Address	ID/FEI	Business Operations
MAS MANAGEMENT GROUP INC.		079363782	label(69677-011)