

**PAIN RELIEVING PATCH ULTRA STRENGTH ULTRA STRENGTH- menthol patch
CVS PHARMACY, 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.

Menthol 5% (Topical Analgesic)

Active Ingredient

Menthol 5%

Purpose

Topical Analgesic

Uses

Temporarily relieves minor aches and pains of muscles and joints associated with:

- arthritis
- simple backache
- strains
- sprains
- bruises

Warnings

For external use only

Do not use

- on wounds or damaged skin
- with a heating pad
- on a child under 12 years of age with arthritis-like conditions

Ask a doctor before use if you

- have redness over the affected area
- are pregnant or breastfeeding

When using this product

- avoid contact with eyes and mucous membranes
- do not bandage tightly
- do not use with a heating pad or other heating device

Stop using this product if

- condition worsens
- excessive skin irritation occurs
- redness is present
- symptoms persist more than 7 days or clear up and occur again within a few days

If pregnant or breastfeeding consult a healthcare professional before use

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

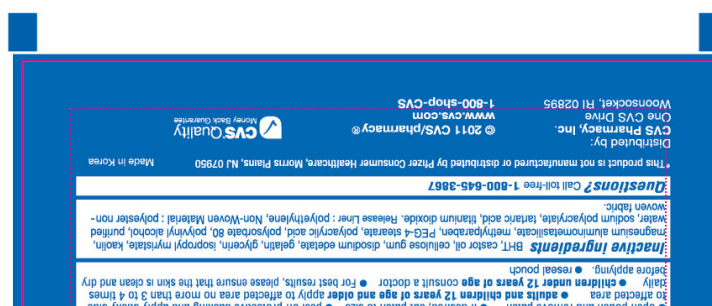
Directions

- open pouch and remove patch

- if desired, cut patch to size
- peel off protective backing and apply sticky side to affected area
- adults and children 12 years of age and older apply to affected area no more than 3 to 4 times daily
- children under 12 years of age consult a doctor
- For best results, please ensure that the skin is clean and dry before applying
- reseal pouch

Inactive Ingredients BHT, castor oil, cellulose gum, disodium edetate, glycerin, isopropyl myristate, kaolin, magnesium aluminummetasilicate, methylparaben, PEG-4 stearate, polyacrylic acid, polysorbate 80, polyvinyl alcohol, purified water, sodium polyacrylate, tartaric acid, titanium dioxide. Release Liner: polyethylene, Non-Woven Material: polyester non-woven fabric.

Questions? Call toll-free 1-800-645-3867



CVS pharmacy

Ultra Strength PAIN RELIEVING PATCH
TOPICAL ANALGESIC
MENTHOL 5%

- Deep, penetrating heat
- Powerful pain relief
- Convenient, no mess

Directions
 Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
 If pregnant or breastfeeding consult a healthcare professional before use.
 Symptoms persist more than 7 days or clear up and occur again within a few days.
 Stop use and ask a doctor if:
 • condition worsens
 • excessive skin irritation occurs
 • redness is present
 • avoid contact with eyes and mucous membranes
 • do not use with a heating pad or other heating device
 When using this product:
 • have redness over the affected area
 • are pregnant or breastfeeding
 Ask a doctor before use if you:
 • on wounds or damaged skin
 • with a heating pad
 • on a child under 12 years of age with arthritis-like conditions
 Do not use:
 • on wounds or damaged skin
 • with a heating pad
 • on a child under 12 years of age with arthritis-like conditions
 For external use only

Warnings
 Backache • strains • sprains • bruises
 Temporarily relieves minor aches and pains of muscles and joints associated with:
 • arthritis • simple

Uses
 Active ingredient: Menthol 5%
 Topical Analgesic

Purpose
 Ultra Strength Pain Relieving Patches provide concentrated deep-penetrating heat in a self-adhesive patch that targets your pain so you have more flexibility and mobility in your muscles and joints. Apply one patch to the site of pain to deliver the relief you need whenever you need it most. Note: The patch will first feel cool before generating a warming sensation. For best results, please ensure that skin is clean and dry before applying. **CONCENTRIC LAYER FOR BEST USE**
 • LOWER BACK • UPPER BACK • SHOULDERS • HIPPS

USA 3446

CVS pharmacy

RESEAL POUCH AFTER OPENING

Compare to the active ingredient in Bengay® Pain Relieving Patch*

Ultra Strength PAIN RELIEVING PATCH
TOPICAL ANALGESIC
MENTHOL 5%

- Deep, penetrating heat
- Powerful pain relief
- Convenient, no mess

LASTS UP TO 8 HOURS!

4 PATCHES IN 1 RESEALABLE POUCH

LARGE SIZE
 Good for Back or Hip
 3.9 IN X 7.9 IN (10 CM X 20 CM)

PAIN RELIEVING PATCH ULTRA STRENGTH ULTRA STRENGTH
 menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-991
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	50 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Silodrate (UNII: 9T3UU8T0QK)	
Butylated Hydroxytoluene (UNII: 1P9D0Z171K)	
Castor Oil (UNII: D5340Y2I9G)	
Carboxymethylcellulose Sodium (UNII: K679OBS311)	
Edetate Disodium (UNII: 7FLD91C86K)	
Gelatin (UNII: 2G86QN327L)	
Glycerin (UNII: PDC6A3C0OX)	
Isopropyl Myristate (UNII: 0RE8K4LNJS)	
Kaolin (UNII: 24H4NWX5CO)	
Methylparaben (UNII: A218C7H9T)	
Peg-4 Stearate (UNII: J33E8608YN)	
Polysorbate 80 (UNII: 6OZP39ZG8H)	
Polyvinyl Alcohol (UNII: 532B59J990)	
Water (UNII: 059QF0K00R)	
Tartaric Acid (UNII: W4888I119H)	
Titanium Dioxide (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-991-01	5 in 1 BOX		
1		1 g in 1 PATCH		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/15/2013	

