

**ULTRA STRENGTH PAIN RELIEF BALM ULTRA STRENGTH- camphor (synthetic)
and menthol ointment
Velocity Pharma LLC**

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.

Ultra strength pain relief balm

Drug Facts

Active Ingredients	Purpose
Camphor 11%	Topical Analgesic
Menthol 11%	Topical Analgesic

Uses

See outer packaging for full uses.

Warnings

For External Use Only

When using this product

- Use only as directed
- Avoid contact with eyes and mucous membranes
- Do not apply to wounds, damaged or irritated skin
- Do not bandage or cover with wrap or use heating pad
- Do not use 1 hour prior to bathing or within 30 minutes after bathing.

Stop use and ask a doctor if

- Condition worsens
- Severe skin irritation occurs
- Pain persists for more than 7 days
- Pain clears up and then recurs a few days later.

If pregnant or breast-feeding, or if you have sensitive skin, ask a healthcare professional before use.

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

Directions

- For adults and children over 12, rub well on the affected area. Repeat 3 to 4 times daily
- For children 12 years of age or younger, consult a doctor before use.

Other information

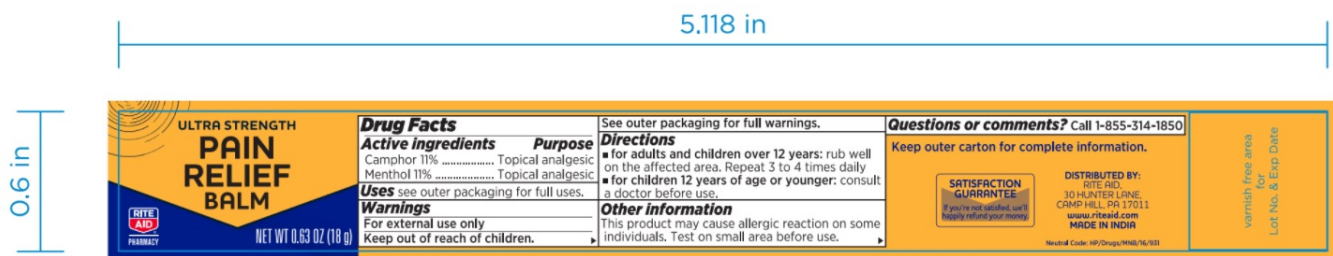
This product may cause allergic reaction on some individuals. Test on small area before use.

Inactive Ingredients

Cajuput Oil, Cassia Oil, Clove Oil, Dementholized Mint Oil and Paraffin base.

Questions

1-855-314-1850



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ULTRA STRENGTH PAIN RELIEF BALM ULTRA STRENGTH

camphor (synthetic) and menthol ointment

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:76168-331

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	110 mg in 1 g
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	110 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CAJUPUT OIL (UNII: J3TO6BUQ37)	
PADANG CASSIA OIL (UNII: 0E15252LIW)	
CLOVE OIL (UNII: 578389D6D0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76168-331-18	1 in 1 PACKAGE	09/10/2020	
1		18 g in 1 JAR; 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	09/10/2020	

Labeler - Velocity Pharma LLC (962198409)

Registrant - Velocity Pharma LLC (962198409)

Revised: 11/2022

Velocity Pharma LLC