STOPAIN MIGRAINE PAIN RELIEVING- mentholum, belladonna, iris versicolor, sanguinaria canadensis gel TROY MANUFACTURING, INC

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

Stopain Migraine Topical Pain Relieving Gel

Drug Facts

Active Ingredients

Mentholum 1X HPUS-50.00%

Belladonna 3X HPUS-1.33%

Iris Versicolor 6X HPUS-1.33%

Sanguinaria Canadensis 6X HPUS-1.33%

Purpose

Migraine Pain

Uses

Temporarily relieves head pain associated with migraine.

Warnings

Ask a doctor before use iif you have

never had migraines diadnosed by a health professional

- Do not apply to broken or irritated skin
- Do not apply to forehead or temples
- **For external use only.** This product should not be used topically on children younger than 2 years of age, nor should it be applied on any mucus membranes of any age child or adult. Seek the advice of your Healthcare professional before using this product topically on children 2 to 12 years of age.
- **Avoid contact with eyes.** If gel gets into eyes or mucus membranes flush with cool water for 1-2 minutes.

Keep out of reach of children.

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

Stop use and consult a doctor if

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

If pregnant or breast-feeding,

ask a health professional before use.

Directions

Adults and children over 12 years:

- Remove cap
- For first application press down several times to prime actuator pump for use
- After actuator has been primed press and release pump once to dispense gel onto finger tips
- Apply to one side on back of neck and behind the ear, repeat for the other side, applying a single pump of product for each side
- For best results, apply as soon as you feel discomfort
- If after 30 minutes the symptoms still persist, reapply as needed, up to 4 times daily.

Inactive Ingredients

Carbopol polymer, ethanol (USP), pentylene glycol, silicone dioxide, triethanolamine, water (USP)

Other Information

Store at room temperature.

Package Labeling:



MENTHOLUM, BELLADONNA, IRIS VERSICOLOR, AND SANGUINARIA CANADENSIS.

For external use only

HOMEOPATHIC

1.62 FL OZ (50mL) 100 PUMPS

Drug Facts

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Mentholum 1X HPUS - 50.00%	Migraine Pain
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Iris Versicolor 6X HPUS – 1.33%	Migraine Pain
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"Uses"

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in 50 mL

for Troy Healthcare, LLC • 130 Lions

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CANADENSIS ROOT

Other Information Store at room temperature.

STOPAIN MIGRAINE PAIN RELIEVING

mentholum, belladonna, iris versicolor, sanguinaria canadensis gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63936-8700
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Route of Administration TOPICAL

CANADENSIS ROOT - UNII:N9288CD508)

Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL -MENTHOL. 1 [hp X] UNII:L7T10EIP3A) UNSPECIFIED FORM in 50 mL ATROPA BELLADONNA (UNII: WQZ3G9PF0H) (ATROPA BELLADONNA -3 [hp_X] ATROPA BELLADONNA UNII:WQZ3G9PF0H) in 50 mL IRIS VERSICOLOR ROOT (UNII: X43D4L3DQC) (IRIS VERSICOLOR ROOT -6 [hp X] IRIS VERSICOLOR ROOT UNII:X43D4L3DQC) in 50 mL SANGUINARIA CANADENSIS ROOT (UNII: N9288CD508) (SANGUINARIA SANGUINARIA 6 [hp_X]

Inactive Ingredients			
Ingredient Name	Strength		
ALCOHOL (UNII: 3K9958V90M)			
PENTYLENE GLYCOL (UNII: 50C1307PZG)			
SILICON DIOXIDE (UNII: ETJ7Z 6XBU4)			

TROLAMINE (UNII: 903K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63936- 8700-1	1 in 1 CARTON	03/20/2015	
1		50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
2	NDC:63936- 8700-2	50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/30/2022	

Marketing Start Date	Marketing End Date
3/20/2015	
	Date

Labeler - TROY MANUFACTURING, INC (160075248)

Registrant - TROY MANUFACTURING, INC (160075248)

Establishment				
Name	Address	ID/FEI	Business Operations	
TROY MANUFACTURING, INC		160075248	manufacture(63936-8700)	

Revised: 1/2023 TROY MANUFACTURING, INC