STOPAIN CLINICAL MIGRAINE AND HEADACHE- menthol, unspecified form, atropa belladonna, iris versicolor root, sanguinaria canadensis root 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 CLINICAL Migraine & Headache

Drug Facts

Active Ingredients

Mentholum 1X HPUS-60.00%

Belladonna 3X HPUS-1.33%

Iris Versicolor 6X HPUS-1.33%

Sanguinaria Canadensis 6X HPUS-1.33%

Purpose

Frontal Headache
Temple/Occiput Pain
Sick Headache
Back of Head Pain

Uses

Temporarily relieves head pain associated with migraine and headache.

Warnings

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 2-12 years of age.

Avoid contact with eyes. If gel gets in eyes or on muscus membranes flush with cool water for 1-2 minutes

Ask a doctor before use if

you have never had migraines diagnosed by a health professional

Do not apply to broken or irritated skin

• Do not apply to forehead or temples

Keep out of reach of children.

If swallowed, get medicial help or contact a Poison Control Center.

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: Tear open packe • Dispense product onto finger tips • Apply to back of neck and behind each ear until product is absorbed • Use entire contents of packet • For best results, apply as soon as you feel discomfort
 If after 30 minutes the symptoms persist, apply second packet

Inactive Ingredients:

Acrylic acid/vinyl ester copolymer, ethanol (USP), hydroxypropylcellulose, pentylene glycol, triethanolamine, water (USP)

Store at room temperature.

Manufactured for Troy Healthcare, LLC • 130 Lions Drive Hazleton, PA 18202 • (800) 201-7246 • stopainclinical.com

Package Labeling:63936-9700-1

Drug Facts
Active Ingredients
Mentholum 1X HPUS-60.00%
Belladonna 3X HPUS-1.33%... PurposeFrontal Headache Temple/Occiput Pain Iris Versicolor 6X HPUS-1 33% Sick Headache Sanguinaria Canadensis 6X HPUS-1.33%..... ..Back of Head Pain Uses Temporarily relieves head pain associated with migraine and headache. Ask a doctor before use if you have never had migraines Ask a doctor before use if you have never nad migraines diagnosed 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 on any mucus membranes of any age child or adult. Seek the advice of your healthcare professional before using this product topically on children 2-12 years of age. Avoid contact with eyes. If gel gels in eyes or on muscus membranes flush with cool water for 1-2 minutes. Keep out of reach of children. If swallowed, get medicial help or

contact a Poison Control Center.

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

Directions

Adults and children over 12 years: Tear open packet ■ Dispense product onto finger tips ■ Apply to back of neck and behind each ear until product is absorbed ■ Use entire contents of packet ■ For best results, apply as soon as you feel discomfort ■ If after 30 minutes the symptoms persist, apply second packet

Inactive Ingredients: Acrylic acid/vinyl ester copolymer, ethanol (USP), hydroxypropylcellulose, pentylene glycol, triethanolamine, water (USP)

Store at room temperature.

Manufactured for Troy Healthcare, LLC ■130 Lions Drive Hazleton, PA
18202 ■ (800) 201-7246 ■ stopainclinical.com

Does Not Contain:

Acetaminophen **Addictive Opioids Aspirin** Caffeine Other NSAIDs

For Best Results:

- Apply as soon as you feel
- discomfort
- If symptoms persist after 30 minutes, apply as needed up to 4 times daily

No known drug interactions.

Claims based upon traditional homeopathic support. The letters 'I-PUS' indicate that the components in this product are officially monographed in the Homeopathic Pharmacopoeia of the United States.



TOPICAL PAIN RELIEVING GEL

HOMEOPATHIC 12 Single 1g Applications For External Use Only

DIRECTIONS FOR USE



packet and dispense gel onto fingertips



Apply to the back of neck and behind each ear until product is absorbed

Use entire contents of packet For best results, apply as soon as you feel discomfort

If after 30 minutes symptoms persist, apply second packet

DO NOT APPLY TO FOREHEAD OR TEMPLES



©2018 Troy Healthcare, LLC 2-565 REV 00

2-746 REV 00 professional before and called and a Directions, Adults and children over 12 years:
Tear open packers in Separas product onto inger tipes
Tear open packers in Separas product onto inger tipes
Apply to back or next and beind read rear until product
is absorbed in See entire contents or packers in or best
minutes may as some as you desconner in all refers
in See insert for more dealist
in Tearlive ingredients-Acrylic activity ester
coopying estimation from the content of the coopying of the Ministration of reach of children. If swallowed, get metch leip or ontaid a Ploson Control Center. Stop use and consult a doctor If a condition worsens or symptoms persign for more than 7 days or clear up and occur again within a few days are decleas is present If pregnant or breast feeding ask a healthcare professional before use Warmings Lake doctor before used if you have management and management of a doctor before use if you have mever had migratines diagnosed by a health professional a Do not apply to broken or inflated skin a Do not apply to broken or inflated skin a Do not apply to broken or inflated skin a Do not apply to broken or inflated skin a Do not apply to broken or inflated skin a Do not apply to forehead or temples. For external use only. This product should not be used topically or influent wourget had be said of special or should not any mucus membranes of any child cautil. Seek the advice of your healthcare professional before using his product topically on children 2 to 12 years of age.

Avoid contact with press. If get gats into eyes or on mucus membranes flush with cool water for 1-2. : Temporarily relieves head pain associated with nes and headaches Active Ingredients
Aenthoum 1X HPUS-60.00%
Jelladonna 3X HPUS-1.33%
its Versicolor 6X HPUS-1.33%
Sanguinaria Canadensis 6X HPUS-1.33%



Single Application

Net WT 1g



Package Labeling: 63936-9700-2



Mentholum 1X HPUS-60.00% Belladonna 3X HPUS-1.33%

Iris Versicolor 6X HPUS-1.33% Sanguinaria Canadensis 6X HPUS-1.33%

Uses: Temporarily relieves head pain associated with migraines and headaches

never had migraines diagnosed by a health professional
■ Do not apply to broken or irritated skin ■ Do not
apply to forehead or temples

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 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 on mucus membranes flush with cool water for 1-2

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

Stop use and consult a doctor if a 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 healthcare

professional before use

Directions: Adults and children over 12 years: Tear open packet■ Dispense product onto fingertips
■ Apply to back of neck and behind each ear until product is absorbed ■ Use entire contents of packet ■ For best results, apply as soon as you feel discomfort

■ If after 30 minutes the symptoms persist, apply second packet ■ See insert for more details

Inactive Ingredients: Acrylic acid/vinyl ester copolymer, ethanol (USP), hydroxypropylcellulose, pentylene glycol, triethanolamine, water (USP)
Store at room temperature.

Manufactured for Troy Healthcare, LLC ■130 Lions Drive

Hazleton, PA 18202 ■ 800 201-7246 ■ stopainclinical.com



STOPAIN CLINICAL MIGRAINE AND HEADACHE

Æ

menthol, unspecified form, atropa belladonna, iris versicolor root, sanguinaria canadensis root gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63936-9700
Route of Administration	TOPICAL		

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

Inactive Ingredients		
Ingredient Name	Strength	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)		
PENTYLENE GLYCOL (UNII: 50C1307PZG)		
TROLAMINE (UNII: 903K93S3TK)		
WATER (UNII: 059QF0KO0R)		

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:63936- 9700-1	12 in 1 BOX	07/01/2018		
1		1 g in 1 PACKET; Type 0: Not a Combination Product			
2	NDC:63936- 9700-2	1 g in 1 PACKET; Type 0: Not a Combination Product	09/30/2022		

Marketing Information			
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
	07/01/2018		
	Application Number or Monograph	Application Number or Monograph Marketing Start Citation Date	

Labeler - Troy Manufacturing, Inc. (160075248)

Registrant - Troy Manufacturing, Inc. (160075248)

Establishment				
Name	Address	ID/FEI	Business Operations	
Troy Manufacturing, Inc.		160075248	manufacture(63936-9700)	

Revised: 1/2023 Troy Manufacturing, Inc.