

HEADON ULTIMATE RELIEF- iris versicolor root and bryonia alba root stick
American Health Distributions 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.

HEADON®

Drug Facts

Active Ingredients	Purpose
Iris versicolor (Blue flag) 12X H.P.U.S. 0.2%	Pain Reliever
Bryonia alba (White bryony) 12X H.P.U.S. 0.08%	Pain Reliever

The letters H.P.U.S. indicate that the components in this product are officially monographed in the Homeopathic Pharmacopoeia of the United States.

Use

- Temporarily relieves the symptoms of headache and migraine pain

Warnings

For external use only

Do not use if you are allergic or hypersensitive to any ingredient in this product, have sensitive skin or any skin disease.

Ask a doctor before use if you have

- never had migraines diagnosed by a health professional
- a headache that is different from your usual migraines
- the worst headache of your life
- headaches beginning after or are caused by head injury, exertion, coughing or bending
- experienced your first headaches after the age of 50
- daily headaches
- migraine headaches so severe as to require bed rest
- fever and stiff neck

When using this product

- avoid contact with eyes, wounds, mucous membranes, broken or irritated skin
- do not share this product with anyone
- do not apply a heating pad to forehead
- irritation or allergic reaction may occur with some people. Test by applying product to a small area of the forehead and wait 30 minutes. If skin appears normal, proceed with Directions.

Stop use and ask a doctor if

- skin redness or irritation develops
- an allergic reaction occurs. Seek medical help right away.
- migraine headache pain worsens or continues for more than 48 hours
- new or unexpected symptoms occur
- ringing in the ears or loss of hearing occurs

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

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

Directions

- Adults and children 12 years and older:
- remove white outer cap
- remove clear inner cap by tilting it to the side
- apply directly to forehead at first sign of headache or migraine
- apply generously covering entire forehead surface area as often as necessary
- Children under 12 years of age: ask a doctor

Other information

Store between 15° and 30° C (59° and 86° F).

Inactive Ingredients

diazolidinyl urea, ethyl alcohol, iodopropynyl butylcarbamate, menthyl lactate, propylene glycol, sodium stearate, steareth-21, tetrasodium EDTA, triethanolamine, water

Dist. by Miralus Healthcare
Cheyenne, WY 82001

Questions ?

call 1-877-373-3436, Weekdays 9AM to 5PM EST or visit us online at www.miralus.com

PRINCIPAL DISPLAY PANEL - 5.67 gram canister carton

NEW

**Apply directly
to forehead**

**HEADON[®]
Headache Relief**

ULTIMATE RELIEF

Headache & Migraine Reliever

NEW



Apply directly to forehead

HEADON[®]

Headache Relief

ULTIMATE RELIEF

Headache & Migraine Reliever

Safe & Effective HEADON[®]
Headache Relief

- Invisible & Non-greasy
- Safe to use with other medications
- Can be used as often as needed

Up to **100**
Applications

Tamper-Evident:
Do Not Use if safety wrap around tube is broken or missing.



HOMEOPATHIC

NET WT 0.20 OZ (5.67 g)

HEADON[®]
Headache Relief

ULTIMATE RELIEF

Keep carton. It contains important information.

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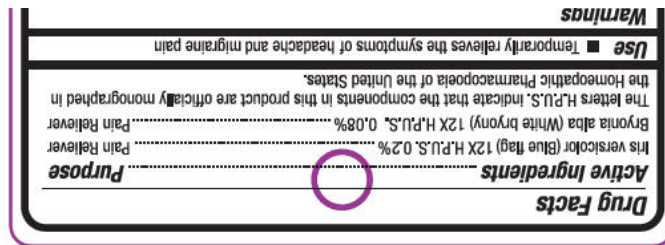
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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67567-0306
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Iris Versicolor Root (UNII: X43D4L3DQC) (Iris Versicolor Root - UNII:X43D4L3DQC)	Iris Versicolor Root	12 [hp_X]
Bryonia Alba Root (UNII: T7J046 YI2B) (Bryonia Alba Root - UNII:T7J046 YI2B)	Bryonia Alba Root	12 [hp_X]

Inactive Ingredients

Ingredient Name	Strength
diazolidinyl urea (UNII: H5RIZ3MPW4)	
alcohol (UNII: 3K9958V90M)	
iodopropynyl butylcarbamate (UNII: 603P14DHEB)	
menthyl lactate (UNII: 2BF9E65L7I)	
propylene glycol (UNII: 6DC9Q167V3)	
sodium stearate (UNII: QU7E2XA9TG)	
EDETATE sodium (UNII: MP1J8420LU)	
trolamine (UNII: 9O3K93S3TK)	
water (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67567-0306-1	1 in 1 CARTON		
1		1 in 1 CANISTER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED HOMEOPATHIC		06/01/2010	

Labeler - American Health Distributions Inc. (010328220)

Establishment

Name	Address	ID/FEI	Business Operations
CPC Laboratories Inc.		026453260	MANUFACTURE, LABEL, PACK

Revised: 6/2010

American Health Distributions Inc.