

## **RAW HEAT- menthol gel**

### **Rescue Dog Health**

*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.*

-----

### **Drug Facts**

#### **Active Ingredient**

Menthol 3.5%

#### **Purpose**

Pain Reliever

#### **Uses**

Temporarily relieves minor pain associated with: muscle sprains, muscle strains, neck/back aches/pains, sore joints, arthritis, cramps and bruises.

#### **Warnings**

For external use only. Flammable. Keep away from open flame or extreme heat. Keep out of reach of children. If swallowed get medical help or contact a poison control center right away. When using this product: Use only as directed. Avoid contact with eyes and mucous membranes. Do not apply to open wounds or damaged skin. Do not bandage tightly. Do not use with a heating pad or other ointments, creams, sprays or liniments. Do not apply to irritated skin. Wash hands thoroughly after each application. Stop use and ask a health professional if condition worsens, if symptoms persist for more than 7 days or clear up and recur again within a few days, or if irritation occurs. If pregnant or breast feeding ask a health care professional before use. Store at room temperature.

#### **Directions**

For adults and children 6 years of age and older: Shake well. Clean skin. Apply a liberal amount of gel directly on the skin over the affected area until absorbed into skin. Repeat as necessary, but not more than 4 times daily. May also be applied before or after activity. For children under 6 years of age, consult a health care professional.

#### **Inactive Ingredients**

Aloe Barbadensis, Cinnamomum Camphora (Camphor) Bark Oil, Cinnamon Cassia (Cassia) Oil, Dehydroxanthan Gum, Gaultheria Procumbens (wintergreen) Leaf Oil, Glycerin, Organic Chamomilla Recutita (Matricaria) Flower Extract, Organic Symphytum Officinale (Comfrey), SDA 38B, Xanthan Gum

#### **Rescue Health, LLC**

Bentonville, AR 72712

[www.rawhealthintl.com](http://www.rawhealthintl.com)

Ph: 1-888-RAW-HLTH

**Questions or comments :**

Email us at: [info@rawhealthintl.com](mailto:info@rawhealthintl.com)

**Principal Display Panel - Bottle Label**

RAW™

HEAT

**100% Natural  
Pain Relief**

**For arthritis, muscle  
and joint pain**

**ROLL-ON GEL**

3 fl OZ/89 mL

<b>Drug Facts</b>	
<b>Active Ingredient</b> Menthol 3.5%	<b>Purpose</b> Pain Reliever
<b>Uses</b> Temporarily relieves minor pain associated with: muscle sprains, muscle strains, neck/back aches/pains, sore joints, arthritis, cramps and bruises.	
<b>Warnings</b> For external use only. Flammable. Keep away from open flame or extreme heat. Keep out of reach of children. If swallowed get medical help or contact a poison control center right away. When using this product: Use only as directed. Avoid contact with eyes and mucous membranes. Do not apply to open wounds or damaged skin. Do not bandage tightly. Do not use with a heating pad or other ointments, creams, sprays or liniments. Do not apply to irritated skin. Wash hands thoroughly after each application. Stop use and ask a health professional if condition worsens, if symptoms persist for more than 7 days or clear up and recur again within a few days, or if irritation occurs. If pregnant or breast feeding ask a health care professional before use. Store at room temperature.	
<b>Directions</b> For adults and children 6 years of age and older: Shake well. Clean skin. Apply a liberal amount of gel directly on the skin over the affected area until absorbed into skin. Repeat as necessary, but not more than 4 times daily. May also be applied before or after activity. For children under 6 years of age, consult a health care professional.	
<b>Inactive Ingredients</b> Aloe Barbadensis, Cinnamomum Camphora (Camphor) Bark Oil, Cinnamon Cassia (Cassia) Oil, Dehydroxanthan Gum, Gaultheria Procumbens (wintergreen) Leaf Oil, Glycerin, Organic Chamomilla Recutita (Matricaria) Flower Extract, Organic Symphytum Officinale (Comfrey), SDA 38B, Xanthan Gum	

**Rescue Health, LLC**  
Bentonville, AR 72712  
[www.rawhealthintl.com](http://www.rawhealthintl.com)  
Ph: 1-888-RAW-HLTH  
Questions or comments:  
Email us at: [info@rawhealthintl.com](mailto:info@rawhealthintl.com)



8 5 9 7 9 7 0 0 3 0 2 8

Containers are BPA Free    Made in the USA    No Animal Testing    100% Recyclable Container ♻️



# HEAT

100% Natural  
Pain Relief

For arthritis, muscle  
and joint pain

ROLL-ON GEL

3 fl OZ / 89 mL

**Principal Display Panel - Bottle Label**

RAW™

HEAT

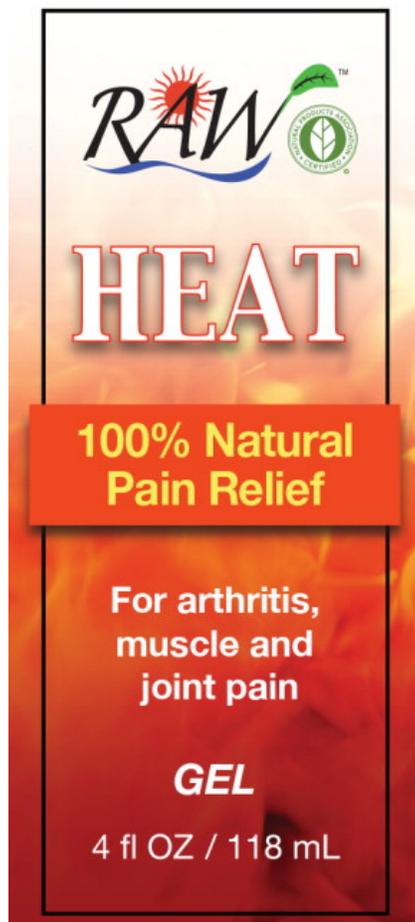
**100% Natural  
Pain Relief**

**For arthritis,**

**muscle and  
joint pain**

**GEL**

4 fl OZ/118 mL



Drug Facts	
Active Ingredient	Purpose
Menthol 3.5%	Pain Reliever
<b>Uses</b> Temporarily relieves minor pain associated with: muscle sprains, muscle strains, neck/back aches/pains, sore joints, arthritis, cramps and bruises.	
<b>Warnings</b> For external use only. <b>Flammable.</b> Keep away from open flame or extreme heat. <b>Keep out of reach of children.</b> If swallowed get medical help or contact a poison control center right away. <b>When using this product:</b> Use only as directed. Avoid contact with eyes and mucous membranes. Do not apply to open wounds or damaged skin. Do not bandage tightly. Do not use with a heating pad or other ointments, creams, sprays or liniments. Do not apply to irritated skin. Wash hands thoroughly after each application. <b>Stop use and ask a health professional</b> if condition worsens, if symptoms persist for more than 7 days or clear up and recur again within a few days, or if irritation occurs. ▶	

8 59797 00300 4

PEEL HERE

Drug Facts (continued)
<b>Warnings (continued)</b> If pregnant or breast feeding ask a health care professional before use. Store at room temperature.
<b>Directions</b> For adults and children 6 years of age and older: Shake well. Clean skin. Apply a liberal amount of gel directly on the skin over the affected area until absorbed into skin. Repeat as necessary, but not more than 4 times daily. May also be applied before or after activity. For children under 6 years of age, consult a health care professional.
<b>Inactive Ingredients</b> Aloe Barbadosensis, Cinnamomum Camphora (Camphor) Bark Oil, Cinnamon Cassia (Cassia) Oil, Dehydroxanthan Gum, Gaultheria Procumbens (wintergreen) Leaf Oil, Glycerin, Organic Chamomilla Recutita (Matricaria) Flower Extract, Organic Symphytum Officinale (Comfrey), SDA 38B, Xanthan Gum

Containers are BPA Free  
Made in the USA No Animal Testing  
100% Recyclable Container ♻️

**Rescue Health, LLC**  
Bentonville, AR 72712  
www.rawhealthintl.com  
Ph: 1-888-RAW-HLTH  
Questions or comments:  
Email us at: info@rawhealthintl.com

**Principal Display Panel - Bottle Label**

**RAW™**

**HEAT**

**100% Natural  
Pain Relief**

**For arthritis, muscle  
and joint pain**

**GEL**

32 fl OZ/946 mL



# HEAT

**100% Natural  
Pain Relief**

**For arthritis, muscle  
and joint pain**

**GEL**

32 fl OZ / 946 mL

## Drug Facts

Active Ingredient	Purpose
Menthol 3.5%	Pain Reliever

**Uses** Temporarily relieves minor pain associated with: muscle sprains, muscle strains, neck/back aches/pains, sore joints, arthritis, cramps and bruises.

**Warnings** For external use only. Flammable. Keep away from open flame or extreme heat. Keep out of reach of children. If swallowed get medical help or contact a poison control center right away. When using this product: Use only as directed. Avoid contact with eyes and mucous membranes. Do not apply to open wounds or damaged skin. Do not bandage tightly. Do not use with a heating pad or other ointments, creams, sprays or liniments. Do not apply to irritated skin. Wash hands thoroughly after each application. Stop use and ask a health professional if condition worsens, if symptoms persist for more than 7 days or clear up and recur again within a few days, or if irritation occurs. If pregnant or breast feeding ask a health care professional before use. Store at room temperature.

**Directions** For adults and children 6 years of age and older: Shake well. Clean skin. Apply a liberal amount of gel directly on the skin over the affected area until absorbed into skin. Repeat as necessary, but not more than 4 times daily. May also be applied before or after activity. For children under 6 years of age, consult a health care professional.

**Inactive Ingredients** Aloe Barbadensis, Cinnamomum Camphora (Camphor) Bark Oil, Cinnamon Cassia (Cassia) Oil, Dehydroxanthan Gum, Gaultheria Procumbens (wintergreen) Leaf Oil, Glycerin, Organic Chamomilla Recutita (Matricaria) Flower Extract, Organic Symphytum Officinale (Comfrey), SDA 38B, Xanthan Gum

Containers are BPA Free  
Made in the USA No Animal Testing  
100% Recyclable Container ♻️



**Rescue Health, LLC**  
Bentonville, AR 72712  
www.rawhealthintl.com  
Ph: 1-888-RAW-HLTH  
Questions or comments:  
Email us at: info@rawhealthintl.com

## RAW HEAT

menthol gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69381-2501
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
menthol (UNII: L7T10EIP3A) (menthol - UNII:L7T10EIP3A)	menthol	3.5 mg in 1 L

### Inactive Ingredients

Ingredient Name	Strength
aloe vera leaf (UNII: ZY81Z83H0X)	
glycerin (UNII: PDC6A3C0OX)	
xanthan gum (UNII: TTV12P4NEE)	
methyl salicylate (UNII: LAV5U5022Y)	
chinese cinnamon oil (UNII: A4WO0626T5)	
camphor oil (UNII: 75IZZ8Y727)	
matricaria recutita (UNII: G0R4UBI2ZZ)	
symphytum uplandicum leaf (UNII: D05HXK6R3G)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69381-2501-1	0.089 L in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69381-2501-2	0.118 L in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:69381-2501-3	0.946 L in 1 BOTTLE; 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	12/18/2014	

**Labeler** - Rescue Dog Health (079558153)

**Registrant** - Safetec of America, Inc. (874965262)

## Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	MANUFACTURE(69381-2501)

Revised: 12/2014

Rescue Dog Health