OCUMEND - arnica montana, ledum palustre Cearna, 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.

Active Ingredients for Vial:

Arnica Montana 52M 50% HPUS

Ledum Palustre 52M 50% HPUS

Active Ingredients for Healing Gels:

Arnica Montana 52M 50% HPUS

Ledum Palustre 52M 50% HPUS

Purpose for Vial:

Arnica Montana 52M 50% HPUS	Bruising
Ledum Palustre 52M 50% HPUS	Black Eve

Purpose for Healing Gels:

Arnica Montana 52M 50%	HPUS	Bruising
Ledum Palustre 52M 50%	HPUS	Black Eye

Uses for Vial:

For the reduction of bruising, swelling and pain.

Uses for Healing Gels:

For the reduction of bruising, swelling and pain.

Warnings for Vial:

For external use only

Warnings for Healing Gels:

For external use only

Do not use for Vial:

Do not use

- in the eyes
- if solution becomes cloudy
- if tamper seal is broken

Do not use for Healing Gels:

Do not use

- in the eyes
- over open wounds
- if you have unexpected bleeding

Stop use for Vial:

Stop use and ask a doctor if condition worsens.

Stop use for Healing Gels:

Stop use and ask a doctor if condition worsens.

Pregnancy Warning for Vial:

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

Pregnancy Warning for Healing Gels:

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

Children Section for Vial:

Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away.

Children Section for Healing Gels:

Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away.

Directions for Vial:

Use as directed by a physician. Pour contents of vial into sterile water. Soak sterile gauze in water mixture and apply to affected site.

Directions for Healing Gels:

Use as directed by a physician. Place healing gels on intact skin and replace as needed.

Other information for Vial:

Store at room temperature. Discard 30 days after opening.

Other information for Healing Gels:

Store at room temperature.

Inactive Ingredients (non-preserved) for Vial:

Citrates, Polysorbate 80, Sodium Chloride, Sterile Water

Inactive Ingredients for Healing Gels:

Acrylates/Acrylamide Co-polymer, Hydroxyethyl Cellulose, Methyldiethanolamine, Water

Questions for Vial:

Call 1-855-223-2762 or Email info@cearna.com

Questions for Healing Gels:

Call 1-855-223-2762 or Email info@cearna.com

The letters HPUS indicate that the component(s) in this product is (are) officially monographed in the Homeopathic Pharmacopeia of the United States.

Do not use if box seal is broken or missing, if peel pouches are open or if band on vial is broken or missing.

CEARNA OCUMEND®

Healing Gels for the Reduction of Bruising, Swelling and Pain

17 – Healing Gel Two-Packs 1 – 0.5 fl oz (15 mL) Sterile Vial

Homeopathic

Drug Facts for Vial	Drug Facts (continued)
Active Ingredients for Vial Arnica Montana 52M 50% HPUS Bruising Ledum Palustre 52M 50% HPUS Black Eye	Directions Use as directed by a physician. Pour contents of vial into sterile water. Soak sterile gauze in water mixture and apply to affected site.
Uses For the reduction of bruising, swelling and pain,	Other Information Store at room temperature, Discard 30 days after opening.
Warnings For external use only	Inactive Ingredients (non-preserved) Citrates, Polysorbate 80, Sodium Chloride, Sterile Water
Do not use • in the eyes • if solution becomes cloudy • if tamper seal is broken Stop use and ask a doctor if condition worsens. If pregnant or breast-feeding ask a health professional before use, Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away.	Questions? Call 1-855-223-2762 or Email info@cearna.com
Drug Facts for Healing Gels	Drug Facts (continued)
Drug Facts for Healing Gels Active Ingredients for Healing Gels Purpose Arnica Montana 50M 50% HPUS Bruising Ledum Palustre 50M 50% HPUS Black Eye	Drug Facts (continued) Directions Use as directed by a physician. Place healing gels on intact skin and replace as needed.
Active Ingredients for Healing Gels Arnica Montana 50M 50% HPUS	Directions Use as directed by a physician. Place healing gels on intact skin
Active Ingredients for Healing Gels Arnica Montana 50M 50% HPUS Bruising Ledum Palustre 50M 50% HPUS Black Eye Uses	Directions Use as directed by a physician. Place healing gels on intact skin and replace as needed. Other Information

The letters 'HPUS' indicate that the component(s) in this product is (are) officially monographed in the Homeopathic Pharmacopeia of the United States, Do not use if box seal is broken or missing, if peel pouches are open or if band on vial is broken or missing.

OCUMEND

arnica montana, ledum palustre kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:76277-211

Packaging

	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:76277-211-61	1 in 1 KIT		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 PACKAGE	17
Part 2	1 VIAL	15 mL

Part 1 of 2

OCUMEND HEALING TWO PACKS

arnica montana, ledum palustre gel

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength Strength
ARNICA MONTANA (UNII: O80TY208ZW) (ARNICA MONTANA - UNI	E:O80TY208ZW) ARNICA MONTANA 52 [hp_M]
LEDUM PALUSTRE TWIG (UNII: 877L01IZ0P) (LEDUM PALUSTRE TV	WIG - UNII:877L01IZ0P) LEDUM PALUSTRE TWIG 52 [hp_M]

Inactive Ingredients	
Ingredient Name	Strength
METHYL DIETHANO LAMINE (UNII: 3IG3K131QJ)	
WATER (UNII: 059QF0KO0R)	

Ш	Packa	ging			
	# Ite	em Code	Package Description	Marketing Start Date	Marketing End Date
	1		17 in 1 PACKAGE		

Marketing InformationMarketing CategoryApplication Number or Monograph CitationMarketing Start DateMarketing End Dateunapproved homeopathic05/17/2012

Part 2 of 2

OCUMEND STERILE VIAL

arnica montana, ledum palustre liquid

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Basis of Strength	Strength		
ARNICA MONTANA	52 [hp_M] in 15 mL		
LEDUM PALUSTRE TWIG	52 [hp_M] in 15 mL		
	ARNICA MONTANA LEDUM PALUSTRE		

Inactive Ingredients	
Ingredient Name	Strength
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WATER (UNII: 059QF0KO0R)	

Pa	ckaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		15 mL in 1 VIAL		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		05/17/2012	
Marketing Information			
Walketing inform			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

Labeler - Cearna, Inc. (968104609)

Registrant - Cearna, Inc. (968104609)

Establishment			
Name	Address	ID/FEI	Business Operations
Katecho, Inc.		139791743	manufacture

Revised: 3/2012 Cearna, Inc.