

CUT AND WOUND REMEDY- topical cut and wound relief spray

Vitality Works, 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.

Olive Leaf Cut & Wound Remedy Spray

Olive Leaf Cut & Wound Remedy

Arnica montana 6X

Calendula officinalis 1X

Hamamelis virginica 3X

Hypericum perforatum 3X

Ledum palustre 3X

Olive Leaf Cut & Wound Remedy

Grapefruit Seed Extract, Olive Leaf Extract (*Olea europaea*), Sodium Chloride, USP Purified Water, Xylitol powder.

Olive Leaf Cut & Wound Remedy

-Do not exceed recommended dosage.

-This product is designed to provide relief and promote healing for superficial cuts and wounds on the surface of the skin. Should the wound be more than superficial seek immediate medical attention.

-For your safety there is a full body seal over bottle printed "sealed for your protection". Do not use if seal is broken or missing.

Olive Leaf Cut & Wound Remedy

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

Olive Leaf Cut & Wound Remedy

A homeopathic remedy for the temporary relief and promotion of rapid healing of the skin for superficial injuries, cuts, punctures, abrasions, lacerations, bites, bruises, sores, stings, and painful wounds.

Olive Leaf Cut & Wound Remedy

-First wash hands and the affected areas of the skin with warm soapy water, rinse and dry.

-Remove protective cap.

-Depress spray pump 2-3 times. Spray on cut or wound covering the entire area.

-When finished wipe nozzle clean and replace cap.

Adults and children 13 years and older - 2-3 sprays, every 2-4 hours or as needed.

Children 3-12 years - Half the adult dose

Children under 3 - Consult healthcare professional

Olive Leaf Cut & Wound Remedy

Arnica montana - Relief for skin injury, bruises, tissue.

Caledula officinalis - Promotes rapid healing of open wounds, superficial burns, sores, abrasions, lacerations, ulcers and suppurating wounds

Hamamelis virginica - Relief for painful wounds, skin injuries, burns, inflammation, and lacerated wounds.

Hypericum perforatum - Relief for punctures and lacerated wounds; tingling, burning, numbness and painful wounds; and bites and bruises of the skin.

Ledum palustre - Promotes healing for puncture wounds; bites, stings, skin eruptions; and discoloration after injuries. Relieves pain after operations.

Olive Leaf Cut & Wound Remedy

Directions for use

- First wash hands and the affected areas of the skin with warm soapy water, rinse, and dry.
- Remove protective cap.
- Depress spray pump 2-3 times. Spray on cut or wound covering the entire area.
- When finished, wipe nozzle clean and replace cap.

Adults and children 13 years and older	2-3 sprays, every 2-4 hours or as needed
Children 3-12 years	Half the adult dose
Children under 3	Consult healthcare professional

Warnings when using this product

- Do not exceed recommended dosage
- If pregnant or breast-feeding, ask a health care professional before use.
- Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

For your safety there is a full body seal over bottle printed "sealed for your protection". Do not use if seal is broken or missing.

To report any serious adverse event, call 1-888-505-4283.

www.Seagateproducts.com

Distr. by: First Fishery Development Services Inc. San Diego, CA 92123



NDC 064616-070-01

SEAGATE OLIVE LEAF

All Natural Ingredients No Chemicals

HOMEOPATHIC

CUT & WOUND REMEDY

For temporary relief of superficial:

- Skin Injuries
- Bruises
- Abrasions
- Lacerations
- Painful Wounds

For External use

1 fl. oz. (30 ml)

Drug Facts (continued)

Directions

- First wash hands and the affected areas of the skin with warm soapy water, rinse, and dry.
- Remove protective cap.
- Depress spray pump 2-3 times. Spray on cut or wound covering the entire area.
- When finished, wipe nozzle clean and replace cap.

Adults and children 13 years and older	2-3 sprays, every 2-4 hours or as needed
Children 3-12 years	Half the adult dose
Children under 3	Consult healthcare professional

Other Information
Store at room temperature. Does not require refrigeration.

Inactive Ingredients
Grapefruit Seed Extract, Olive Leaf Extract (Olea europaea), Sodium Chloride, USP Purified Water, Xylitol Powder.

Drug Facts (continued)

Questions?
Call 1-888-505-4283 toll-free in U.S., 24 hrs. 7 days/week.

Drug Facts

Active Ingredients **Purpose**

Arnica montana 6X.....Relief for skin injury, bruises, tissue degeneration, itching, and burning.

Calendula officinalis tincture.....Promotes rapid healing of open wounds, superficial burns, sores, abrasions, lacerations, ulcers and suppurating wounds.

Hamamelis virginica 3X.....Relief for painful wounds, skin injuries, lacerations, inflammation, and lacerated wounds.

Hypericum perforatum 3X.....Relief for punctures and lacerated wounds, tingling, burning, stinging, and painful wounds, and bites and bruises of the skin.

Ledum palustre 3X.....Promotes healing for puncture wounds, bites, stings, skin eruptions, and discoloration after injuries. Relieves pain after operations.

Uses

- A homeopathic remedy for the temporary relief and promotion of rapid healing of the skin for: superficial injuries, cuts, punctures, abrasions, lacerations, bites, bruises, sores, stings, and painful wounds.

Drug Facts (continued)

Warnings

When using this product

- Do not exceed recommended dosage.
- This product is designed to provide relief and promote healing for superficial cuts and wounds on the surface of the skin. Should the wound be more than superficial, seek immediate medical attention.
- For your safety there is a full body seal over bottle printed "sealed for your protection". Do not use if seal is broken or missing.
- If pregnant or breast-feeding, ask a health care professional before use.
- Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

SEAGATE OLIVE LEAF

HOMEOPATHIC

CUT & WOUND REMEDY

NDC 064616-070-01

SEAGATE OLIVE LEAF

All Natural Ingredients No Chemicals

HOMEOPATHIC

CUT & WOUND REMEDY



Temporary Relief of Superficial:

- Skin Injuries
- Bruises
- Abrasions
- Lacerations
- Painful Wounds

A Water-based Natural Remedy
1 fl. oz. (30 ml)



Strong enough for adults, gentle enough for children.

Homeopathy is a natural approach to medicine that stimulates the body's curative responses so that the body helps to heal itself.

Natural homeopathic products derived from plant sources are proving to be potent preventatives, treatments and stimulants of the body's natural immune system. This product does not contain any pharmaceutical drug.

Established in 1981 Seagate produces a variety of natural raw materials derived from their fishing and farming operations. These raw materials are the ingredients for a variety of Seagate's products that include:

- Cold and Flu Remedies
- Diet and Colon Cleanse
- Fish Fertilizer
- Healthy Heart and Circulation
- Immune Support
- Joint Support
- Tea
- Topical Skin Care
- Vegetable and Fruit Concentrates

Contact Seagate for a free product catalog:
1-888-505-GATE or visit
www.SeagateProducts.com

To report any serious adverse event, call 1-888-505-4283.

Distributed by:
First Fishery Development Services Inc.
San Diego, CA 92123

CUT AND WOUND REMEDY

topical cut and wound relief spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:646 16-070
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
ARNICA MONTANA (UNII: Q80TY2087W)	ARNICA MONTANA - UNII:Q80TY2087W	ARNICA MONTANA	6 [hp_X]

ARNICA MONTANA (UNII: 060112082W) (ARNICA MONTANA - UNII:060112082W)	ARNICA MONTANA	in 1 mL
CALENDULA OFFICINALIS FLOWERING TOP (UNII: 18E7415PXQ) (CALENDULA OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)	CALENDULA OFFICINALIS FLOWERING TOP	1 [hp_X] in 1 mL
HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK (UNII: T7S323PKJS) (HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK - UNII:T7S323PKJS)	HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK	3 [hp_X] in 1 mL
HYPERICUM PERFORATUM (UNII: XK4IUX8MNB) (HYPERICUM PERFORATUM - UNII:XK4IUX8MNB)	HYPERICUM PERFORATUM	3 [hp_X] in 1 mL
LEDUM PALUSTRE TWIG (UNII: 877L01IZ0P) (LEDUM PALUSTRE TWIG - UNII:877L01IZ0P)	LEDUM PALUSTRE TWIG	3 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CITRUS PARADISI SEED (UNII: 12F08874Y7)	
OLEA EUROPAEA LEAF (UNII: MJ95C30H47)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
WATER (UNII: 059QF0K00R)	
XYLITOL (UNII: VCQ006KQ1E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64616-070-02	1 in 1 CARTON	07/18/2011	
1	NDC:64616-070-01	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		07/18/2011	

Labeler - Vitality Works, Inc. (137752817)

Registrant - Vitality Works, Inc. (137752817)

Establishment

Name	Address	ID/FEI	Business Operations
Vitality Works, Inc.		137752817	manufacture(64616-070)