

PERIACTIVE- sambucus nigra flower, echinacea purpurea, and centella asiatica mouthwash
Izun Pharmaceutical Corporation

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.

PeriActive®

Drug Facts:

| Active Ingredients (in each 15ml) | Purposes |
|--|--|
| ▪ Sambucus nigra 3x | Irritation/gingivitis reducer gum repair stimulator |
| ▪ Echinacea purpurea 4x | Irritation/gingivitis reducer |
| ▪ Hydrocotyle asiatica 4x | Irritation/gingivitis reducer |

Uses

- Helps protect against gingivitis
- Helps reduce gum bleeding and soreness
- Helps reduce plaque formation
- Helps reduce gum inflammation
- Promotes gingival healing

Warnings

Allergy alert

Do not use if allergic to any of the ingredients. Stop use and ask a dentist if:

- gingivitis, bleeding, or redness persists for more than 2 weeks
- you have painful or swollen gums, pus from the gum line, loose teeth, or increasing spacing between the teeth. These may be the signs of periodontitis, a serious form of gum disease.

Keep out of reach of children under 6 years of age.

In case more than is used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

| | |
|--|--|
| adults and children 12 years and older | rinse for 60 seconds with 15ml (3 teaspoonful) twice a day |
| children 6-12 years | rinse for 60 seconds with 10ml (2 teaspoonful) twice a day |
| children under 6 years of age | do not use |

- do not eat, drink or rinse your mouth for 30 minutes after use

- do not swallow
- children 6 years to under 12 years of age: supervise use

Other information

This rinse is not intended to replace brushing or flossing

- store at room temperature 15-30°C (59-86°F)
- keep out of direct sunlight
- do not use if tab is broken, breached or missing

Inactive ingredients

cetylpyridinium chloride, cool mint flavor¹, disodium EDTA, FD&C Blue No. 1, lactic acid, maltodextrin, menthol, nat. cinnamon flavor¹, PEG-40 hydrogenated castor oil, propylene glycol, sodium benzoate, sorbitol, sucralose, water, wintergreen flavor¹

¹ contains one or more of these ingredients

Questions?

Call 1-877-210-2621 Monday thru Friday 8am-5pm EST

Distributed by: **Izun Oral Care, Inc.**, New York, NY 10020 USA

PRINCIPAL DISPLAY PANEL - 500 mL Bottle Label

PeriACTIVE®

ADVANCED GUM CARE

ORAL RINSE

Powered by Nature

CLINICALLY PROVEN

to Reduce Inflammation

KILLS BACTERIA

REDUCES

Gum Bleeding & Soreness

PROTECTS

Against Plaque & Gingivitis

Fresh Mint

HOMEOPATHIC

Safety-sealed for your protection.

500 mL (16.9 fl. oz.)

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v2017

PA500HUSL v.4; No

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Printed above, on bottle

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©2017, Izun Oral Care *contains one or more of these ingredients

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| | | | |
|--|----------------|---------------------------|---------------|
| PERIACTIVE | | | |
| sambucus nigra flower, echinacea purpurea, and centella asiatica mouthwash | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:49589-111 |

| | | | | |
|--|---|---|-----------------------------|---------------------------|
| Route of Administration | TOPICAL | | | |
| Active Ingredient/Active Moiety | | | | |
| | Ingredient Name | Basis of Strength | Strength | |
| | Sambucus nigra flower (UNII: 07V4DX094T) (Sambucus nigra flower - UNII:07V4DX094T) | Sambucus nigra flower | 3 [hp_X] in 1 mL | |
| | Echinacea purpurea (UNII: QI7G114Y98) (Echinacea purpurea - UNII:QI7G114Y98) | Echinacea purpurea | 4 [hp_X] in 1 mL | |
| | Centella asiatica (UNII: 7M867G6T1U) (Centella asiatica - UNII:7M867G6T1U) | Centella asiatica | 4 [hp_X] in 1 mL | |
| Inactive Ingredients | | | | |
| | Ingredient Name | Strength | | |
| | cetylpyridinium chloride (UNII: D9OM4SK49P) | | | |
| | edetate disodium (UNII: 7FLD91C86K) | | | |
| | LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT) | | | |
| | maltodextrin (UNII: 7CVR7L4A2D) | | | |
| | polyoxyl 40 hydrogenated castor oil (UNII: 7YC686GQ8F) | | | |
| | propylene glycol (UNII: 6DC9Q167V3) | | | |
| | sodium benzoate (UNII: OJ245FE5EU) | | | |
| | sorbitol (UNII: 506T60A25R) | | | |
| | sucralose (UNII: 96K6UQ3ZD4) | | | |
| | water (UNII: 059QF0K00R) | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:49589-111-50 | 12 in 1 CARTON | 01/11/2009 | |
| 1 | | 500 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 2 | NDC:49589-111-10 | 100 mL in 1 BOTTLE; Type 0: Not a Combination Product | 11/01/2019 | |
| Marketing Information | | | | |
| | Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| | UNAPPROVED HOMEOPATHIC | | 01/11/2009 | |

Labeler - Izun Pharmaceutical Corporation (624194523)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------|---------|-----------|------------------------|
| LC Beauty | | 338857935 | MANUFACTURE(49589-111) |