

IZUN PERIACTIVE MOUTHWASH- sambucus nigra flower extract, centella asiatica leaf extract, echinacea purpurea extract mouthwash

Izun Pharmaceuticals Corporation

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Izun Periactive Mouthwash

Active ingredient

Sambucus nigra flower extract, 3x

Centella Asiatica Leaf Extract, 4x

Echinacea Purpurea Extract, 4x

Inactive Ingredients:

Aqua, Propylene Glycol, Sorbitol, PEG-40 Hydrogenated Castor Oil, Cetylpyridinium Chloride, Lactic Acid, Sodium Benzoate, Disodium EDTA, Maltodextrin, Sucralose, CI 42090, Aroma

Irritation / gingivitis reducer / gum repair reducer

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 15 ml (3 teaspoonful twice a day)
children 6-12 years	rinse for 60 seconds with 10 ml (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

Uses

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

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

- Sambucus nigra 3x Irritation/gingivitis reducer
gum repair stimulator
- Echinacea purpurea 4x . . . Irritation/gingivitis reducer
- Hydrocotyle asiatica 4x . . . Irritation/gingivitis reducer

PA500HUSL v.4; No

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- Helps reduce plaque formation
- Promotes gingival healing
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Printed above, on bottle



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

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

Distributed by: Izun Oral Care, Inc., New York, NY 10020 USA, www.izunoralcare.com

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

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

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.)

Drug Facts:

Active Ingredients (in each 15ml) Purposes

©2017

sambucus nigra flower extract, centella asiatica leaf extract, echinacea purpurea extract mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49589-112
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CENTELLA ASIATICA LEAF (UNII: 6810070TYD) (CENTELLA ASIATICA LEAF - UNII:6810070TYD)	CENTELLA ASIATICA LEAF	4 [hp_X] in 1 mL
ECHINACEA PURPUREA (UNII: QI7G114Y98) (ECHINACEA PURPUREA - UNII:QI7G114Y98)	ECHINACEA PURPUREA	4 [hp_X] in 1 mL
SAMBUCUS NIGRA FLOWER (UNII: 07V4DX094T) (SAMBUCUS NIGRA FLOWER - UNII:07V4DX094T)	SAMBUCUS NIGRA FLOWER	3 [hp_X] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM BENZOATE (UNII: OJ245FE5EU)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
LACTIC ACID (UNII: 33X04XA5AT)	
BRILLIANT BLUE G (UNII: MIZRX790SI)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Product Characteristics

Color	blue	Score	
Shape		Size	
Flavor	WINTERGREEN	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49589-112-01	500 mL in 1 TUBE; Type 0: Not a Combination Product	08/24/2018	
2	NDC:49589-112-02	75 mL in 1 TUBE; Type 0: Not a Combination Product	08/24/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/24/2018	

Labeler - Izun Pharmaceuticals Corporation (624194523)

Establishment

Name	Address	ID/FEI	Business Operations
Incos Cosmeceutica Industriale Srl		434933032	manufacture(49589-112)

Revised: 1/2019

Izun Pharmaceuticals Corporation