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

**Incos Cosmeceutica Industriale Srl** 

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.

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#### 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, Cetylpyridinum Chloride, Lactic Acid, Sodium Benzoate, Disodium EDTA, Maltodextrin, Sucralose, CI 42090, Aroma

Irritation / gingivitus 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

6 years of age

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

 $\mathbb{X}$ 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 NDC:49589-111 HUMAN OTC DRUG Item Code (Source) Product Type

# **PeriACTIVE®**

## **ADVANCED** GUM CARE

**ORAL RINSE** 

Powered by Nature



## **CLINICALLY PROVEN**

to Reduce Inflammation

**KILLS BACTERIA** 

## **REDUCES**

Gum Bleeding & Soreness

## **PROTECTS**

Against Plaque & Gingivitis



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

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72549-000
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: M1ZRX790SI)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)			
CETYLPYRIDINIUM CHLO RIDE (UNII: D9 O M4SK49 P)			
MALTO DEXTRIN (UNII: 7CVR7L4A2D)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)			

Product Characteristics			
Color	blue	Score	
Shape		Size	
Flavor	WINTERGREEN	Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:72549-000-01	500 mL in 1 TUBE; Type 0: Not a Combination Product	0 1/3 1/2 0 19	
2	NDC:72549-000-02	75 mL in 1 TUBE; Type 0: Not a Combination Product	0 1/3 1/2 0 19	

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

## **Labeler** - Incos Cosmeceutica Industriale Srl (434933032)

Establishment			
Name	Address	ID/FEI	Business Operations
Incos Cosmeceutica Industriale Srl		434933032	manufacture(72549-000)

Revised: 1/2019 Incos Cosmeceutica Industriale Srl