

## **HALODINE ORAL ANTISEPTIC- povidone-iodine spray**

**Halodine Llc**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

-----

### **Halodine Oral Antiseptic Spray**

#### ***Drug Facts***

##### ***Active Ingredient***

Povidone-Iodine USP, 1.25%

(0.125% Available Iodine)

##### ***Purpose***

Antiseptic

**Uses** • Oral Antiseptic • First aid to help prevent infection in minor oral irritation caused by dental procedures

##### ***Warnings For external use only.***

**Do not use** • If allergic to iodine • In the eyes • On children less than 3 years old • For more than 7 days unless directed by a dentist or doctor **Stop use and promptly ask your dentist or doctor** if sore mouth symptoms do not improve within 7 days, if irritation, pain, or redness persists or worsens, or if swelling, rash, or fever develops.

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

***Directions*** For oral antiseptics in adults and children 3 years of age and older:

1. Press down pump completely and spray twice into mouth. 2. Swish vigorously in mouth for 15 seconds. 3. Slightly lift chin and tilt head back to gargle. Spit out excess. Children under 3 years of age: Consult a dentist or doctor

***Other Information*** • Not made with natural rubber latex • Store at room temperature; avoid excessive heat

***Inactive Ingredients*** hydroxyethylcellulose, purified water

***Questions or comments?*** [contact@halodine.com](mailto:contact@halodine.com)

**Povidone-Iodine USP, 1.25%**

☐ **Helps Reduce Risk of Infection**

**4-Hour Formula**

**halodine.com**

□PATENT PENDING

Manufactured in the U.S.A.

for Halodine LLC 111 NE 1st St,

Ste 806, Miami, FL 33132

**Packaging**

Halodine

Halodine

Oral Antiseptic Spray  
Povidone-Iodine USP, 1.25%  
2fl oz (60ml)

Helps Reduce  
Risk of Infection  
4-Hour Formula

NDC: 78371-401-01

Halodine

Oral Antiseptic Spray  
Povidone-Iodine USP, 1.25%  
2fl oz (60ml)

Helps Reduce  
Risk of Infection  
4-Hour Formula

halodine.com  
PATENT PENDING

Halodine

Oral Antiseptic Spray  
Povidone-Iodine USP, 1.25%  
2fl oz (60ml)

Helps Reduce  
Risk of Infection  
4-Hour Formula

Manufactured in the U.S.A.  
for Halodine LLC 111 NE 1st St,  
Ste 806, Miami, FL 33132



LOT  
EXP

**Drug Facts**

**Active Ingredient Purpose**  
Povidone-Iodine USP, 1.25%..... Antiseptic  
(0.125% Available Iodine)

**Uses** ■ Oral Antiseptic ■ First aid  
to help prevent infection in minor oral irritation  
caused by dental procedures

**Warnings** For external use only.

**Do not use** ■ If allergic to iodine  
■ In the eyes ■ On children less than 3  
years old ■ For more than 7 days unless  
directed by a dentist or doctor

**Stop use and promptly ask your dentist  
or doctor** if sore mouth symptoms do not  
improve within 7 days.

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

**Directions**

For oral antiseptics in adults and children 3  
years of age and older:  
1. Press down pump completely and spray  
twice into mouth.  
2. Swish vigorously in mouth for 15 seconds.  
3. Slightly lift chin and tilt head back to  
gargle. Spit out excess.

Children under 3 years of age: Consult a  
dentist or doctor

**Other Information** ■ Not made  
with natural rubber latex ■ Store at room  
temperature; avoid excessive heat

**Inactive Ingredients**  
hydroxyethylcellulose, purified water

**Questions or comments?**  
contact@halodine.com

# Halodine

## Oral Antiseptic Spray Povidone-Iodine USP, 1.25%

2fl oz (60ml)

### Helps Reduce Risk of Infection 4-Hour Formula

[halodine.com](http://halodine.com)

PATENT PENDING

Manufactured in the U.S.A.  
for Halodine LLC 111 NE 1st St,  
Ste 806, Miami, FL 33132

NDC: 78371-401-01

#### Active Ingredient

Povidone-Iodine USP, 1.25%.....Antiseptic  
(0.125% Available Iodine)

**Uses** ■ Oral Antiseptic ■ First aid to help prevent infection  
in minor oral irritation caused by dental procedures

#### Warnings For external use only.

**Do not use** ■ If allergic to iodine ■ In the eyes ■ On  
children less than 3 years old ■ For more than 7 days unless  
directed by a dentist or doctor **Stop use and promptly  
ask your dentist or doctor** if sore mouth symptoms do not  
improve within 7 days, if irritation, pain, or redness persists  
or worsens, or if swelling, rash, or fever develops. **Keep out  
of reach of children.** If large amounts swallowed, get medical  
help or contact a Poison Control Center right away.

**Directions** For oral antiseptics in adults and children 3 years  
of age and older:

1. Press down pump completely and spray twice into mouth.
2. Swish vigorously in mouth for 15 seconds.
3. Slightly lift chin and tilt head back to gargle. Spit out excess. Children under 3 years of age: Consult a dentist or doctor

**Other Information** ■ Not made with natural rubber latex  
■ Store at room temperature; avoid excessive heat

**Inactive Ingredients** hydroxyethylcellulose, purified water  
**Questions or comments?** [contact@halodine.com](mailto:contact@halodine.com)

## HALODINE ORAL ANTISEPTIC

povidone-iodine spray

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78371-401
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	1.25 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
WATER (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
---	-----------	---------------------	----------------------	--------------------

1	NDC:78371-401-01	60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	10/01/2020	
---	------------------	---	------------	--

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	10/01/2020	

**Labeler** - Halodine Llc (117526113)

Revised: 10/2020

Halodine Llc