AURODONE POVIDONE IODINE 5 % OPTHALMIC SOLUTION- povidone iodine 5 % topical solution solution Aurolab

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.

ACTIVE INGREDIENT

Povidone Iodine IP 5% w/v.

INACTIVE INGREDIENT

- 1. Citric acid
- 2. Disodium hydrogen O- phosphate, Potassium iodate
- 3. Glycerin
- 4. Purified water

USE

- For preparation of the skin prior to surgery
- Helps reduce bacteria that potentially can

cause skin infection

QUESTIONS

Call. 1-800-103-7321,

E-mail: info@aurolab.com Web: www.aurolab.com

KEEP OUT OF REACH OF CHILDREN

If swallowed get medical help or contact a Poison Control Center right away.

STOP USE

Irritation, sensitization, or allergic reaction occurs and lasts for 72 hours. These may be signs of a serious condition.

DO NOT USE

 If you are allergic to povidone-iodine or any other ingredients in this preparation In the eyes

WARNINGS

For External use only

INDIACATIONS AND USAGE

Prolonged exposure to wet solution may cause irritation or, rarely, severe skin reactions
In pre-operative prepping, avoid "pooling" beneath the patient

Purpose

Antiseptic

Dose

- Clean the area and apply product to the operative site prior to surgery.
- The solution can be used to irrigate the cornea and conjunctiva with a sterile bulb syringe prior to surgery.
- After the solution has been left in contact for two minutes flush the residual prep solution using a sterile saline solution.

PACKAGE CARTON



Issue:01-12/2022

Drug Facts Active Ingredient Purpose Povidone Iodine IP 5% w/v... Use For preparation of the skin prior to surger ■ Helps reduce bacteria that potentially can cause skin infection Warnings For external use only Do not use ■ If you are allergic to povidone-iodine or any other ingredients in this preparation In the eves When using this product ■ Prolonged exposure to wet solution may cause irritation or, rarely, severe skin reactions

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■Irritation, sensitization, or allergic reaction

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Aurolab, No. 1 sivagangai Main Road

Veerapanjan, Madurai-625020, India

beneath the patient

Manufactured by:

Made In India. Mfg.Lic.No:TN00002387

Stop use and ask a doctor if

be signs of a serious condition.



NDC Code: 16030-601-05

Povidone Iodine

Solution IP 5% w/v

aurolab

Drug Facts (continued) Directions

- Clean the area and apply product to the operative site prior to surgery.
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- After the solution has been left in contact for two minutes flush the residual prep solution using a sterile saline solution.

Inactive Ingredients Citric acid, Disodium hydrogen O- phosphate, Potassium iodate, Glycerin, Purified water

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

For your protection a tamper evident ring is attached to the bottle cap. Upon opening, this ring will separate from the cap and can be discarded. Use only if this ring is present and attached when the bottle is first opened





Povidone lodine Solution IP 5% w/v

AURODONE

STERILE 5 ml Preparative Solution



Batch No. Mfg. Date

Exp. Date

AURODONE POVIDONE IODINE 5 % OPTHALMIC SOLUTION

povidone iodine 5 % topical solution solution

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:16030-601

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)

IODINE

5 mg in 1 mL

Inactive Ingredients				
Ingredient Name	Strength			
GLYCERIN (UNII: PDC6A3C0OX)				
WATER (UNII: 059QF0KO0R)				
CITRIC ACID ACETATE (UNII: DSO12WL7AU)				
POTASSIUM IODATE (UNII: 1139E44NHL)				

DISODIUM HYDROGEN CITRATE (UNII: 6FO62KCQ7A)

Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:16030-601- 05	5 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2023	

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333E	01/31/2023			
IIIIai					

Labeler - Aurolab (677319965)

Establishment					
Name	Address	ID/FEI	Business Operations		
Aurolab		677319965	manufacture(16030-601)		

Revised: 1/2023 Aurolab