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

1. 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

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**	**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: I139E44NHL)	

DISODIUM HYDROGEN CITRATE (UNII: 6FO62KCQ7A)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	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	

Labeler - Aurolab (677319965)

Establishment

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

Revised: 1/2023 Aurolab