DYNAREX POVIDONE IODINE PREP SOLUTION- povidone iodine prep solution liquid
Dynarex Corporation

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.

1413, 1414, 1415, 1416

Active Ingredient

Povidone-iodine 10%

Purpose

Healthcare Antiseptic

Use

For preparation of the skin prior to surgery. Helps reduce bacteria that potentially can cause skin infection

Warnings

For external use only

Do Not Use
- if allergic to iodine
- in the eyes

Stop use and ask a doctor if
- irritation and redness develop
- condition persists for more than 72 hours

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

Directions

Clean the area. Apply product to the operative site prior to surgery.

Other

Store at controlled room temperature.

Inactive Ingredients

Citric Acid, Disodium Phosphate, Glycerin, Puried Water, Sodium Citrate, Tween 80

Questions?

1-888-DYNAREX

Labeling

A fast acting, broad spectrum, and persistent antiseptic containing preparation that significantly reduces the number of micro-organisms on intact skin.

Drug Facts

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Questions? 1-888-DYNAREX

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Manufactured for:
Dynarex Corporation
10 Glenshaw Street
Orangeburg, NY 10962
USA • www.dynarex.com

Made in Mexico

Reorder No. 1413

dynarex

Povidone Iodine Prep Solution U.S.P.

Preoperative Skin Preparation

4 fl. oz. (118 ml)

DYNAREX POVIDONE IODINE PREP SOLUTION

povidone iodine prep solution liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67777-141
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	10 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	

CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
WATER (UNII: 059QF0KO0R)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-141-31	48 in 1 CASE	05/08/2018	
1	NDC:67777-141-30	118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:67777-141-41	24 in 1 CASE	05/08/2018	
2	NDC:67777-141-40	237 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:67777-141-51	24 in 1 CASE	05/08/2018	
3	NDC:67777-141-50	473 mL in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:67777-141-61	4 in 1 CASE	05/08/2018	
4	NDC:67777-141-60	3790 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/08/2018	

Labeler - Dynarex Corporation (008124539)

Revised: 12/2022 Dynarex Corporation