PERINEZE TRIPLE DYE - brilliant green, proflavine hemisulfate, gentian violet solution
Peace Medical Inc.

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.

Drug Facts

Active Ingredients (in each dose)

Brilliant green 2.29 mg

Proflavine hemisulfate 1.14 mg

gentian violet 2.29 mg

Purpose

Prevent Infection

Use

aids in the prevention of infection in the umbilical cord area of newborn

Contraindications

none

Warnings

for external use only

KEEP OUT OF REACH OF CHILDREN

Directions

- Peel paper portion of package down over base of ampule
- Avoid touching tip during removal
- With tip in downward position, pinch center to crush ampule.
- Apply to area to be prepped using accepted technique.
- Discard as non-hazardous waste.

Other information

store at controlled room temperature 15-30ºC (58-86ºF)

Inactive ingredients

aqueous solution

Perineze Triple Dye Package Label

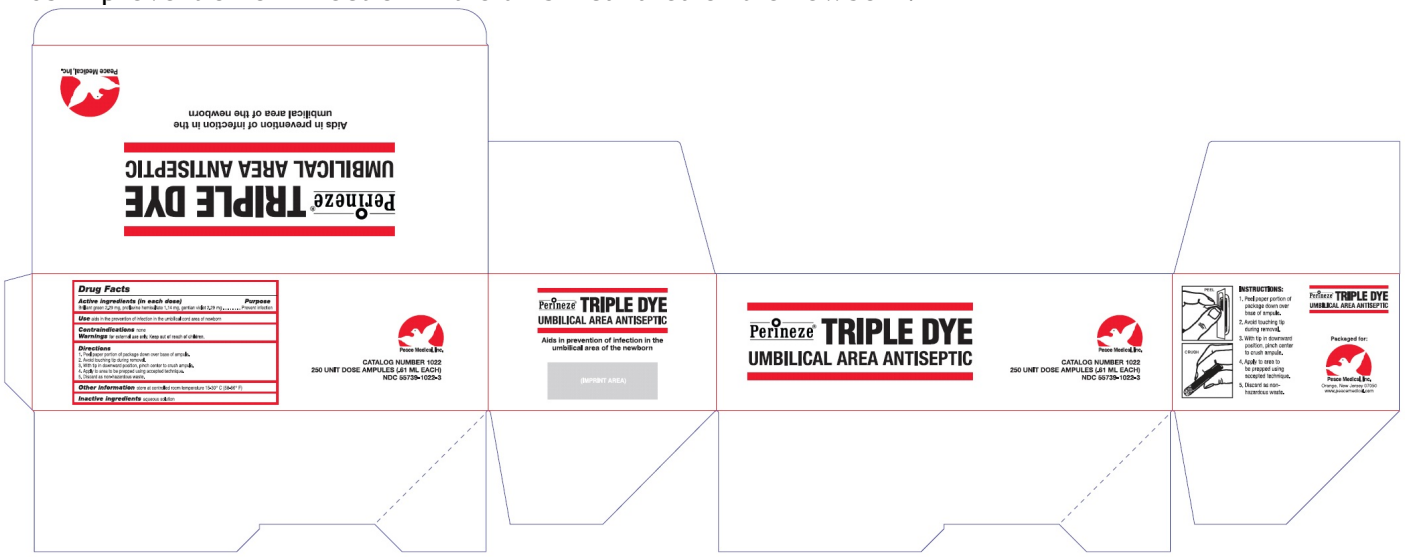
Perineze® Triple Dye

UMBILICAL AREA ANTISEPTIC

Peace Medical, Inc.

CATALOG NUMBER 1022
250 UNIT DOSE AMPULES (.61 ML EACH)
NDC 55739-1022-3

Aids in prevention of infection in the umbilical area of the newborn.



PERINEZE TRIPLE DYE

brilliant green, proflavine hemisulfate, gentian violet solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55739-1022
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BRILLIANT GREEN (UNII: G0L543D370) (BRILLIANT GREEN - UNII:G0L543D370)	BRILLIANT GREEN	2.29 mg in 0.61 mL
PROFLAVINE HEMISULFATE (UNII: 27V8M747VB) (PROFLAVINE HEMISULFATE - UNII:27V8M747VB)	PROFLAVINE HEMISULFATE	1.14 mg in 0.61 mL
GENTIAN VIOLET (UNII: J4Z741D6O5) (GENTIAN VIOLET - UNII:J4Z741D6O5)	GENTIAN VIOLET	2.29 mg in 0.61 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:55739-1022-3	250 in 1 BOX		

1		0.61 mL in 1 AMPULE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	09/28/2011	

Labeler - Peace Medical Inc. (010906881)

Establishment

Name	Address	ID/FEI	Business Operations
Peace Medical Inc.		010906881	manufacture

Revised: 9/2011 Peace Medical Inc.