

PURGO ULTRA PC - chloroxylenol soap
Certus 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.

Purgo Ultra PC 6176 Drug Facts and Label

Drug Facts Box OTC-Active Ingredient Section

Chloroxylenol 0.6%

Drug Facts Box OTC-Purpose Section

Antiseptic

Drug Facts Box OTC-Indications & Usage Section

for hand-washing to decrease bacteria on the skin

Drug Facts Box OTC-Warnings Section

For external use only

Drug Facts Box OTC-When Using Section

do not get into eyes

if contact occurs, rinse eyes thoroughly with water

Drug Facts Box OTC-Stop Use Section

irritation and redness develop

Drug Facts Box OTC-Keep Out of Reach of Children Section

if swallowed, get medical help or contact a Poison Control Center right away

Drug Facts Box OTC-Dosage & Administration Section

wet hands and forearms

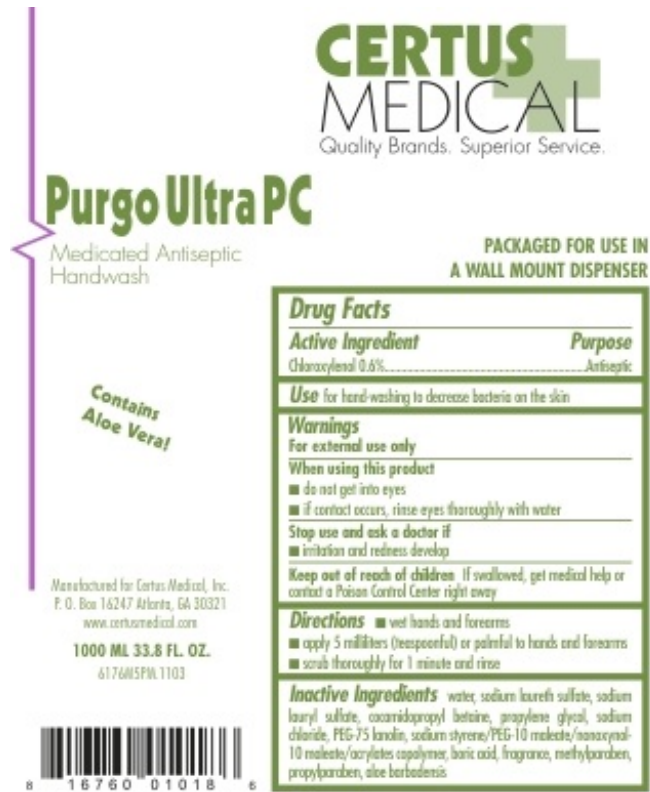
apply 5 milliliters (teaspoonful) or palmful to hands and forearms

scrub thoroughly for 1 minute and rinse

Drug Facts Box OTC-Inactive Ingredient Section

water, sodium laureth sulfate, sodium lauryl sulfate, cocamidopropyl betaine, propylene glycol, sodium chloride, PEG-75 lanolin, sodium styrene/PEG-10 maleate/nonoxynol-10 maleate/acrylates copolymer, boric acid, fragrance, methylparaben, propylparaben, aloe barbadensis

Purgo Ultra PC 6176 1000ml



6176M5PM.jpg Purgo Ultra PC 1000ml

PURGO ULTRA PC			
chloroxylenol soap			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75990-300
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)		CHLOROXYLENOL	6 mg in 1 mL
Inactive Ingredients			
Ingredient Name			Strength
WATER (UNII: 059QF0K00R)			
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)			
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
SODIUM CHLORIDE (UNII: 451W47IQ8X)			
ALOE VERA LEAF (UNII: ZY81Z83H0X)			
PROPYLPARABEN (UNII: Z8IX2SC1OH)			
METHYLPARABEN (UNII: A2I8C7HI9T)			
BORIC ACID (UNII: R57ZHV85D4)			
SODIUM LAURYL SULFATE (UNII: 368GB5141J)			

PEG-75 LANOLIN (UNII: 09179OX7TB)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75990-300-06	1 in 1 BOX		
1		800 mL in 1 BAG		
2	NDC:75990-300-17	532 mL in 1 BOTTLE, PLASTIC		
3	NDC:75990-300-24	118 mL in 1 BOTTLE, PLASTIC		
4	NDC:75990-300-01	1200 mL in 1 CARTRIDGE		
5	NDC:75990-300-03	350 mL in 1 CARTRIDGE		
6	NDC:75990-300-05	540 mL in 1 BOTTLE, PLASTIC		
7	NDC:75990-300-07	700 mL in 1 BAG		
8	NDC:75990-300-09	2000 mL in 1 CARTRIDGE		
9	NDC:75990-300-10	1000 mL in 1 CARTRIDGE		
10	NDC:75990-300-11	1000 mL in 1 BOTTLE, PLASTIC		
11	NDC:75990-300-12	1000 mL in 1 BAG		
12	NDC:75990-300-13	800 mL in 1 BAG		
13	NDC:75990-300-14	3785 mL in 1 BOTTLE, PLASTIC		
14	NDC:75990-300-15	946 mL in 1 BOTTLE, PLASTIC		
15	NDC:75990-300-28	149 mL in 1 BOTTLE, PLASTIC		
16	NDC:75990-300-27	800 mL in 1 CARTRIDGE		
17	NDC:75990-300-55	2082 mL in 1 DRUM		
18	NDC:75990-300-08	1 in 1 BOX		
18		1000 mL in 1 BAG		
19	NDC:75990-300-16	236 mL in 1 BOTTLE, PLASTIC		
20	NDC:75990-300-18	50 mL in 1 BOTTLE, PLASTIC		
21	NDC:75990-300-19	1890 mL in 1 CONTAINER		
22	NDC:75990-300-20	7560 mL in 1 DRUM		
23	NDC:75990-300-35	1325 mL in 1 DRUM		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph not final	part333E	04/25/2011	

Labeler - Certus Medical, Inc. (966433653)

Registrant - ABC Compounding Co., Inc. (003284353)

Establishment

Name	Address	ID/FEI	Business Operations
ABC Compounding Co., Inc.		003284353	manufacture