

PURGO ULTRA - triclosan 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 6953 Drug Facts and Label

Drug Facts Box OTC-Active Ingredient Section

Triclosan 0.3%

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, alcohol denat., propylene glycol, tetrasodium EDTA, PEG-75 lanolin, boric acid, lauramine oxide, chloroxylenol, methylparaben, propylparaben, fragrance, aloe barbadensis, acid red 1, reactive green 12

Purgo Ultra 6953 1000ml



6953M5PM.jpg Purgo Ultra 1000ml

PURGO ULTRA			
triclosan soap			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75990-572
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	3.0 mg in 1 mL	
Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)			
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)			
BORIC ACID (UNII: R57ZHV85D4)			
ALCOHOL (UNII: 3K9958V90M)			
CHLOROXYLENOL (UNII: 0F32U78V2Q)			
ALOE VERA LEAF (UNII: ZY81Z83H0X)			
PROPYLPARABEN (UNII: Z8IX2SC10H)			
METHYLPARABEN (UNII: A2I8C7HI9T)			

SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
LAURAMINE OXIDE (UNII: 4F6FC4M18W)	
PEG-75 LANOLIN (UNII: 09179OX7TB)	
EDETATE SODIUM (UNII: MP1J8420LU)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75990-572-06	1 in 1 BOX		
1		800 mL in 1 BAG		
2	NDC:75990-572-17	532 mL in 1 BOTTLE, PLASTIC		
3	NDC:75990-572-24	118 mL in 1 BOTTLE, PLASTIC		
4	NDC:75990-572-01	1200 mL in 1 CARTRIDGE		
5	NDC:75990-572-03	350 mL in 1 CARTRIDGE		
6	NDC:75990-572-05	540 mL in 1 BOTTLE, PLASTIC		
7	NDC:75990-572-07	700 mL in 1 BAG		
8	NDC:75990-572-09	2000 mL in 1 CARTRIDGE		
9	NDC:75990-572-10	1000 mL in 1 CARTRIDGE		
10	NDC:75990-572-11	1000 mL in 1 BOTTLE, PLASTIC		
11	NDC:75990-572-12	1000 mL in 1 BAG		
12	NDC:75990-572-13	800 mL in 1 BAG		
13	NDC:75990-572-14	3785 mL in 1 BOTTLE, PLASTIC		
14	NDC:75990-572-15	946 mL in 1 BOTTLE, PLASTIC		
15	NDC:75990-572-28	149 mL in 1 BOTTLE, PLASTIC		
16	NDC:75990-572-27	800 mL in 1 CARTRIDGE		
17	NDC:75990-572-55	208200 mL in 1 DRUM		
18	NDC:75990-572-08	1 in 1 BOX		
18		1000 mL in 1 BAG		
19	NDC:75990-572-16	236 mL in 1 BOTTLE, PLASTIC		
20	NDC:75990-572-18	50 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/29/2011	

Labeler - Certus Medical, Inc. (966433653)

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

Establishment

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