PREVENS - triclosan soap
ABC Compounding Co., 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.

Prevens 6364 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 chloride, 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

Prevens 6364 18 oz

636418PS.jpg Prevens 18 oz

PREVENS

triclosan soap

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:62257-364
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	0.003 mL in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
BORIC ACID (UNII: R57ZHV85D4)	
ALCOHOL (UNII: 3K9958V90M)	
CHLOROXYLENOL (UNII: 0F32U78V2Q)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:62257-364-06	1 in 1 BOX		

1		800 mL in 1 BAG		
2	NDC:62257-364-17	532 mL in 1 BOTTLE, PLASTIC		
3	NDC:62257-364-24	118 mL in 1 BOTTLE, PLASTIC		
4	NDC:62257-364-01	1200 mL in 1 CARTRIDGE		
5	NDC:62257-364-03	350 mL in 1 CARTRIDGE		
6	NDC:62257-364-05	540 mL in 1 BOTTLE, PLASTIC		
7	NDC:62257-364-07	700 mL in 1 BAG		
8	NDC:62257-364-09	2000 mL in 1 CARTRIDGE		
9	NDC:62257-364-10	1000 mL in 1 CARTRIDGE		
10	NDC:62257-364-11	1000 mL in 1 BOTTLE, PLASTIC		
11	NDC:62257-364-12	1000 mL in 1 BAG		
12	NDC:62257-364-13	800 mL in 1 BAG		
13	NDC:62257-364-14	3785 mL in 1 BOTTLE, PLASTIC		
14	NDC:62257-364-15	946 mL in 1 BOTTLE, PLASTIC		
15	NDC:62257-364-28	149 mL in 1 BOTTLE, PLASTIC		
16	NDC:62257-364-27	800 mL in 1 CARTRIDGE		
17	NDC:62257-364-55	208200 mL in 1 DRUM		
18	NDC:62257-364-08	1 in 1 BOX		
18		1000 mL in 1 BAG		
19	NDC:62257-364-16	236 mL in 1 BOTTLE, PLASTIC		
20	NDC:62257-364-18	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	11/01/2010	

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

Establishment

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

Revised: 12/2010 ABC Compounding Co., Inc.