

PHARMA CLEANSE HAND SANITIZER- hand sanitizer gel
Ballistic LLC

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.

Pharma Cleanse HAND SANITIZER

ACTIVE INGREDIENTS:

ETHYL ALCOHOL 75%

PURPOSE

ANTISEPTIC

USES:

HELPS REDUCE BACTERIA ON THE SKIN. RECOMMENDED FOR REPEATED USE.

WARNINGS:

FOR EXTERNAL USE ONLY. FLAMMABLE. KEEP AWAY FROM FIRE OR FLAME. WHEN USING THIS PRODUCT, AVOID CONTACT WITH EYES. IN CASE OF CONTACT WITH EYES, FLUSH THOROUGHLY WITH WATER. AVOID CONTACT WITH BROKEN SKIN. STOP USE AND SEEK MEDICAL ADVICE IF IRRITATION OR REDNESS DEVELOPS, OR IF 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.

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DIRECTIONS:

DISPENSE ONE PUMP OF SANITIZER ON TO HANDS AND RUB TOGETHER UNTIL DRY. USE AS NEEDED. FOR CHILDREN UNDER 6, USE WITH ADULT SUPERVISION. NOT RECOMMENDED FOR INFANTS.

OTHER INFO:

STORE BELOW 110 (DEGREES FAHRENHEIT). MAY CAUSE DISCOLORATION TO CERTAIN FABRICS AND SURFACES.

INACTIVE INGREDIENTS:

WATER (AQUA), CARBOMER, TRIETHANOLAMINE.

Package Label

40ml, NDC: 78528-001-01

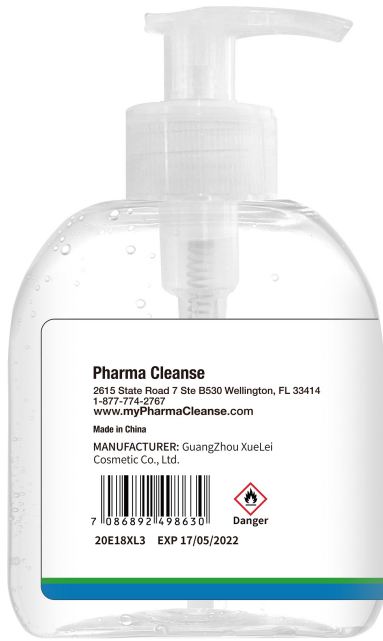


60ml, NDC: 78528-001-02



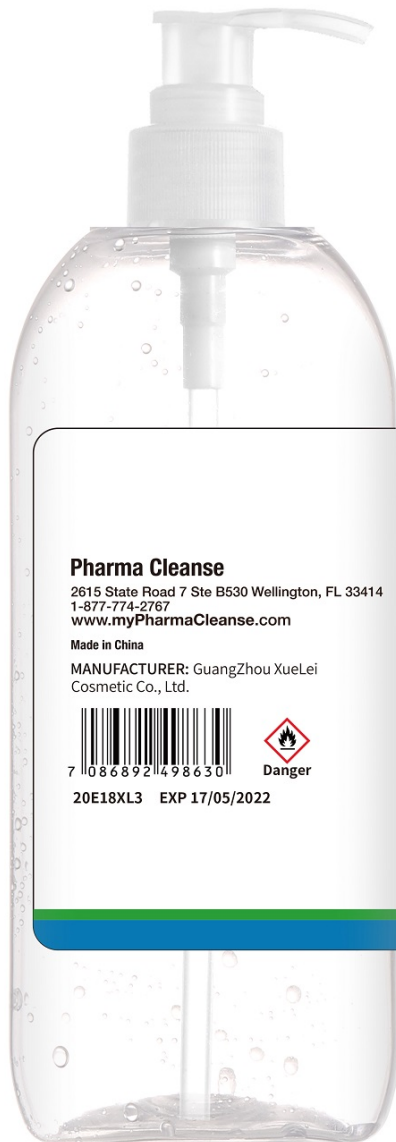
60ml

500ml, NDC: 78528-001-03



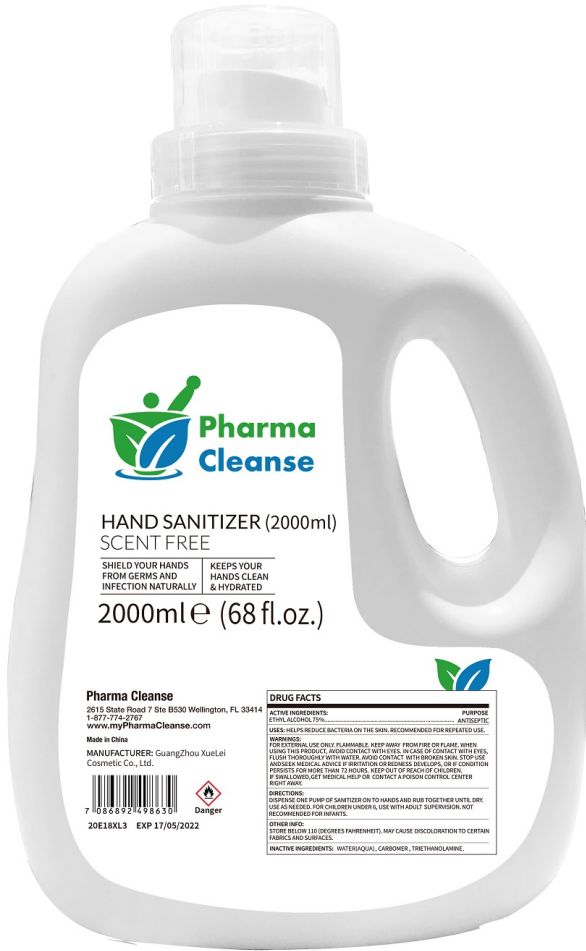
500ml

1000ml, NDC: 78528-001-04



1000ml

2000ml, NDC: 78528-001-05



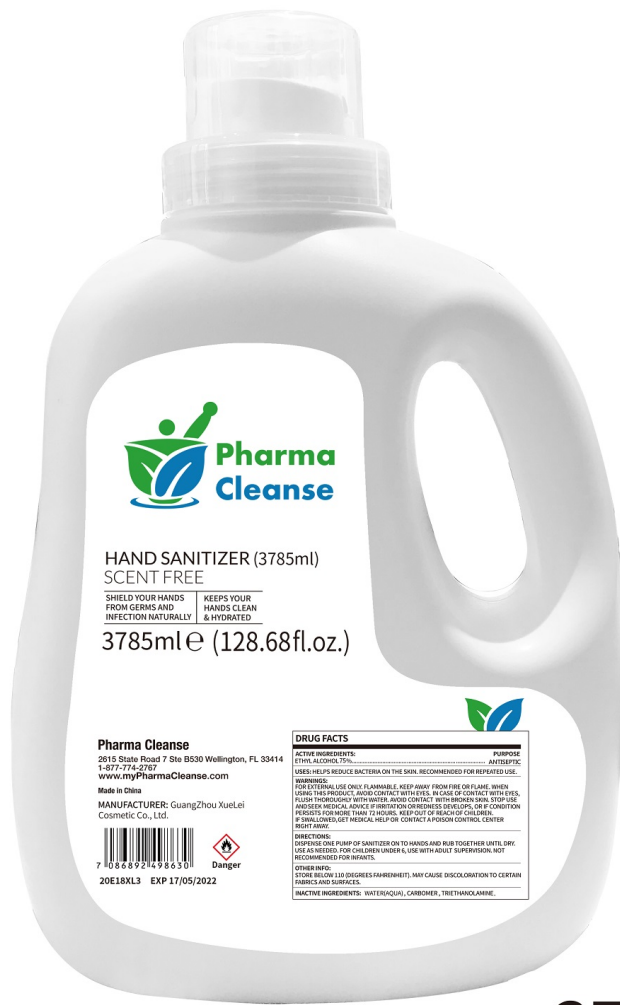
正面



2000ml

背面

3785ml, NDC: 78528-001-06



正面

3785ml



背面

PHARMA CLEANSE HAND SANITIZER

hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78528-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	22.19 g in 100 mL

CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	0.4 g in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.22 g in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78528-001-01	40 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2020	
2	NDC:78528-001-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2020	
3	NDC:78528-001-03	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/18/2020	
4	NDC:78528-001-04	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/18/2020	
5	NDC:78528-001-05	2000 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2020	
6	NDC:78528-001-06	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/18/2020	

Labeler - Ballistic LLC (117441744)

Registrant - GUANGZHOU XUELEI COSMETIC CO.,LTD. (526885026)

Establishment

Name	Address	ID/FEI	Business Operations
GUANGZHOU XUELEI COSMETIC CO.,LTD.		526885026	manufacture(78528-001) , pack(78528-001) , label(78528-001)

Revised: 11/2021

Ballistic LLC