ORAPAZ- cephalexin, ibuprofen, chlorhexidine gluconate
Brisk Pharmaceuticals

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Orapaz

Rx Only

NDC 73614-417-03

ORAPAZ™
Each Pack Contains:
Cephalexin Capsules, USP 500 mg - One 30 ct Bottle
Ibuprofen Tablets, USP 800 mg - One 30 ct Bottle
Chlorhexidine Gluconate Oral Rinse, USP 0.12% - Two 118 ml Bottles

Brisk Pharmaceuticals

Packaged by:

Unit Dose Solutions Inc.,

Morrisville, NC 27560

Distributed by:

Brisk pharmaceuticals,

Richardson, TX 75081

Keep out of reach of children.

Storage: Store at 20°C to 25°C

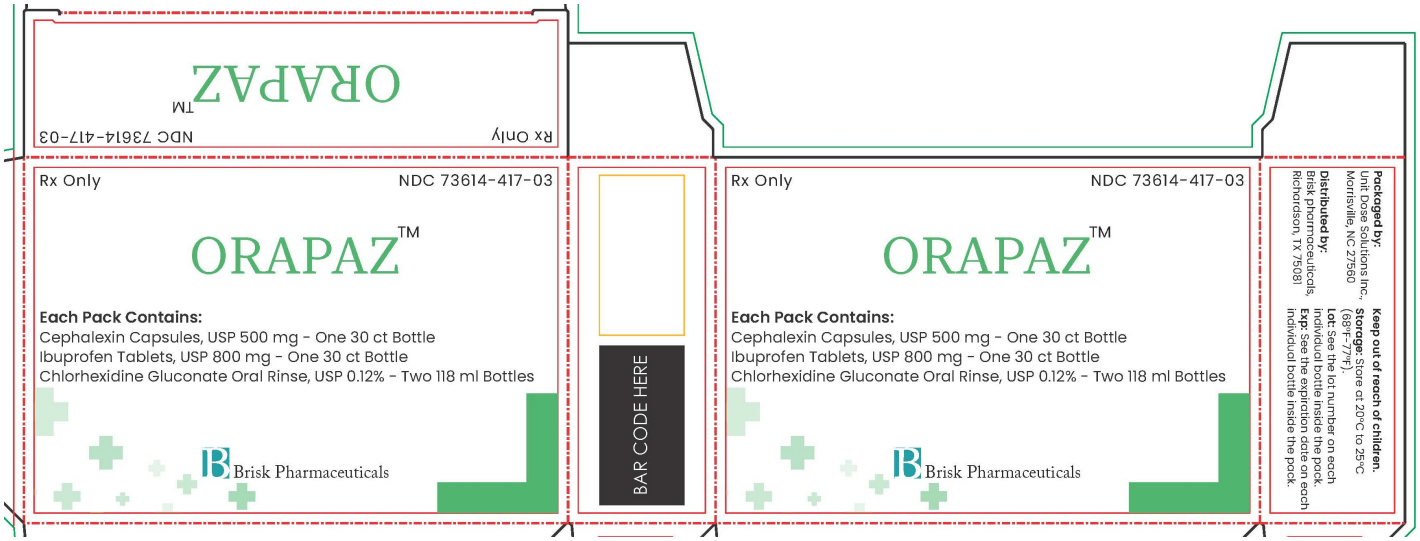
(68°F-77°F).

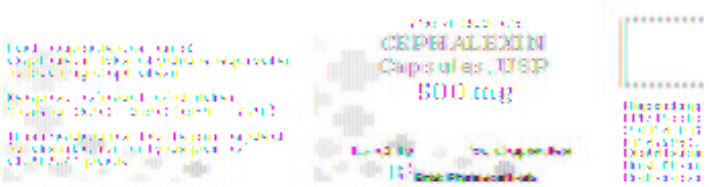
Lot: See the lot number on each

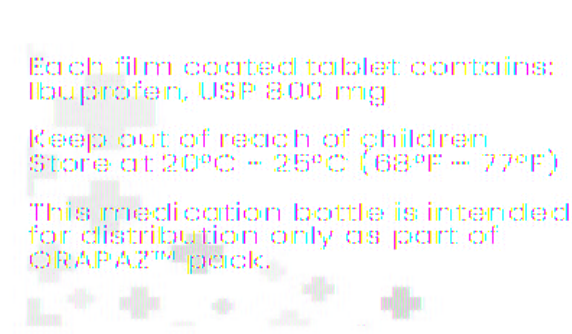
individual bottle inside the pack.

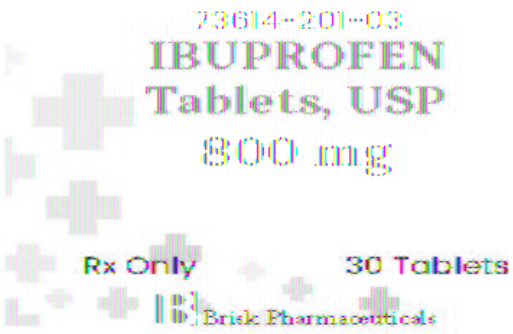
Exp: See the expiration date on each

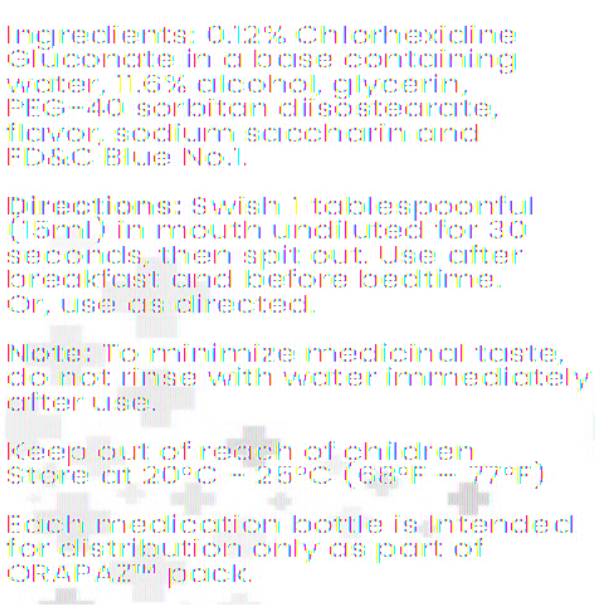
individual bottle inside the pack.

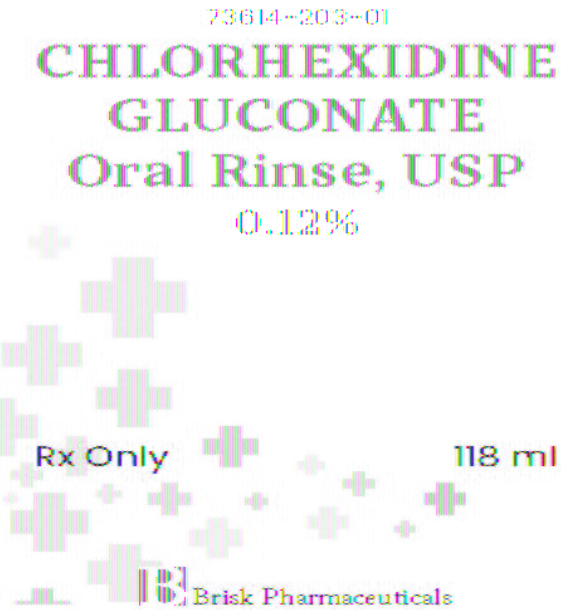

ORAPAZ™
Rx Only
NDC 73614-417-03
Rx Only
NDC 73614-417-03
ORAPAZ™
Each Pack Contains:
Cephalexin Capsules, USP 500 mg - One 30 ct Bottle
Ibuprofen Tablets, USP 800 mg - One 30 ct Bottle
Chlorhexidine Gluconate Oral Rinse, USP 0.12% - Two 118 ml Bottles
Brisk Pharmaceuticals
BAR CODE HERE
Rx Only
NDC 73614-417-03
ORAPAZ™
Each Pack Contains:
Cephalexin Capsules, USP 500 mg - One 30 ct Bottle
Ibuprofen Tablets, USP 800 mg - One 30 ct Bottle
Chlorhexidine Gluconate Oral Rinse, USP 0.12% - Two 118 ml Bottles
Brisk Pharmaceuticals
Packaged by:
Unit Dose Solutions Inc.,
Morrisville, NC 27560
Distributed by:
Brisk Pharmaceuticals,
Richardson, TX 75081
Keep out of reach of children.
Storage: Store at 20°C to 25°C (68°F-77°F).
Lot: See the lot number on each individual bottle inside the pack.
Exp: See the expiration date on each individual bottle inside the pack.


CEPHALEXIN
Capsules, USP
500 mg


Each film coated tablet contains:
Ibuprofen, USP 800 mg
Keep out of reach of children
Store at 20°C - 25°C (68°F - 77°F)
This medication bottle is intended for distribution only as part of ORAPAZ™ pack.


73614-201-03
IBUPROFEN
Tablets, USP
800 mg
Rx Only
30 Tablets
Brisk Pharmaceuticals


Ingredients: 0.12% Chlorhexidine Gluconate in a base containing water, 11.6% alcohol, glycerin, PEG-40 sorbitan diisostearate, flavor, sodium saccharin and FD&C Blue No.1.
Directions: Swish 1 tablespoonful (15ml) in mouth undiluted for 30 seconds, then spit out. Use after breakfast and before bedtime. Or, use as directed.
Note: To minimize medicinal taste, do not rinse with water immediately after use.
Keep out of reach of children
Store at 20°C - 25°C (68°F - 77°F)
Each medication bottle is intended for distribution only as part of ORAPAZ™ pack.


73614-203-01
CHLORHEXIDINE
GLUCONATE
Oral Rinse, USP
0.12%
Rx Only
118 ml
Brisk Pharmaceuticals

ORAPAZ

cephalexin, ibuprofen, chlorhexidine gluconate kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:73614-417

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:73614-417-03	1 in 1 CARTON; Type 1: Convenience Kit of Co-Package	02/10/2025	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BOTTLE	118 mL
Part 2	1 BOTTLE	30
Part 3	1 BOTTLE	30
Part 4	1 BOTTLE	118 mL

Part 1 of 4

CHLORHEXIDINE GLUCONATE ORAL RINSE

chlorhexidine gluconate oral rinse solution

Product Information	
Item Code (Source)	NDC:73614-203
Route of Administration	DENTAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	1.2 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ALCOHOL (UNII: 3K9958V90M)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
PEG-40 SORBITAN DIISOSTEARATE (UNII: JL4CCU7I1G)	

Product Characteristics			
Color	blue	**Score**	
Shape		**Size**	
Flavor	MINT	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:73614-203-01	118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075561	07/27/2023	

Part 2 of 4

CEPHALEXIN

cephalexin capsule

Product Information	
Item Code (Source)	NDC:73614-202
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CEPHALEXIN (UNII: OBN7UDS42Y) (CEPHALEXIN ANHYDROUS - UNII:5SFF1W6677)	CEPHALEXIN ANHYDROUS	500 mg

Inactive Ingredients	
Ingredient Name	**Strength**
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	

CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Product Characteristics			
Color	green (Dark Green Opaque, Light Green Opaque)	**Score**	no score
Shape	CAPSULE	**Size**	21mm
Flavor		**Imprint Code**	A;43;500;mg
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73614-202-03	30 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA065253	11/16/2005	

Part 3 of 4

IBUPROFEN

ibuprofen tablet, film coated

Product Information	
Item Code (Source)	NDC:73614-201
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	800 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics			
Color	white	**Score**	no score
Shape	OVAL (CAPLET)	**Size**	19mm
Flavor		**Imprint Code**	BI8
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73614-201-03	30 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202413	05/23/2024	

Part 4 of 4

CHLORHEXIDINE GLUCONATE ORAL RINSE

chlorhexidine gluconate oral rinse solution

Product Information	
Item Code (Source)	NDC:73614-203
Route of Administration	DENTAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	1.2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	

GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
PEG-40 SORBITAN DIISOSTEARATE (UNII: JL4CCU7I1G)	

Product Characteristics

Color	blue	**Score**	
Shape		**Size**	
Flavor	MINT	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73614-203-01	118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075561	07/27/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/10/2025	

Labeler - Brisk Pharmaceuticals (117250794)

Revised: 2/2025 Brisk Pharmaceuticals