CETIRIZINE HCL- cetirizine tablet
CETIRIZINE HCL- cetirizine
GLENMARK THERAPEUTICS INC., USA

Drug Facts

Cetirizine HCl 5 mg

Cetirizine HCl 10 mg

Antihistamine

Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose,
- sneezing,
- itchy, watery eyes,
- itching of the nose or throat

Do not use if you have ever had an allergic reaction to this product or any of its ingredients or an antihistamine containing hydroxyzine

Ask a doctor before useif you have liver or kidney disease.

Your doctor should determine if you need a different dose.

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives

When using this product

- drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if an allergic reaction to this product occurs. Seek medical help right away.

If pregnant or breast-feeding:

- If breast-feeding: not recommended
- if pregnant: ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222)

Cetirizine Hydrochloride Tablets, USP 5 mg

adults and children 6 years and over	1 tablet (5 mg) or 2 tablets (10) once daily depending upon severity of symptoms; do not take more than 2 tablets (10) in 24

	hours.
adults 65 years and over	1 tablet (5 mg) once a day; do not take more than 1 tablet (5 mg) in 24 hours.
children under 6 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

Cetirizine Hydrochloride Tablets, USP 10 mg

adults and children 6 years and over	one 10 mg tablet once daily; do not take more than one 10 mg tablet in 24 hours. A 5 mg product may be appropriate for less severe symptoms.
adults 65 years and over	ask a doctor
children under 6 years of age	ask a doctor
consumers with liver or kidney disease	ask a doctor

Other information

- store between 20°C to 25°C (68°F to 77°F)
- **do not use of imprinted foil inner seal on bottle is broken or missing.**
- FDA approved organic impurities test procedure differs from USP

colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide

Questions or comments?

call toll-free weekdays 9 AM to 5 PM EST at **1 (888) 721-7115**

Manufactured by:

Glenmark Pharmaceuticals Limited

Pithampur, Madhya Pradesh 454775, India

Distributed by:

Glenmark Therapeutics Inc., USA

Mahwah, NJ 07430

Product of India

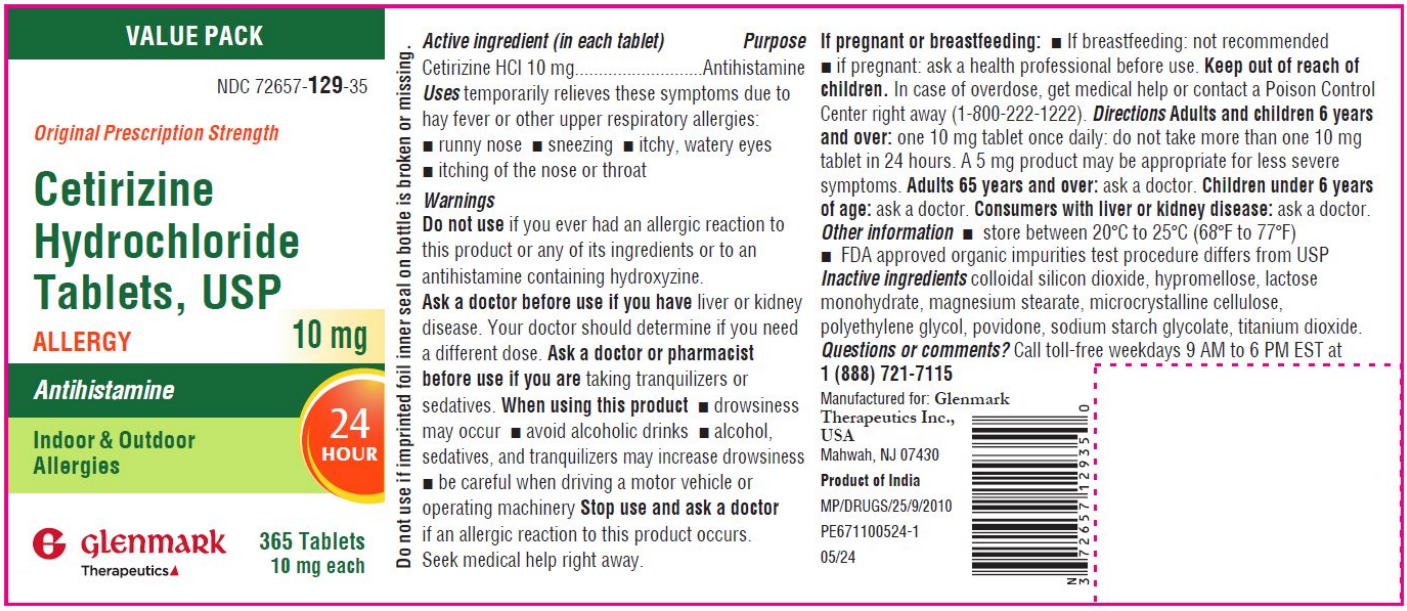
February 2024

Package/Label Principal Display Panel

Container label

NDC 72657-129-35

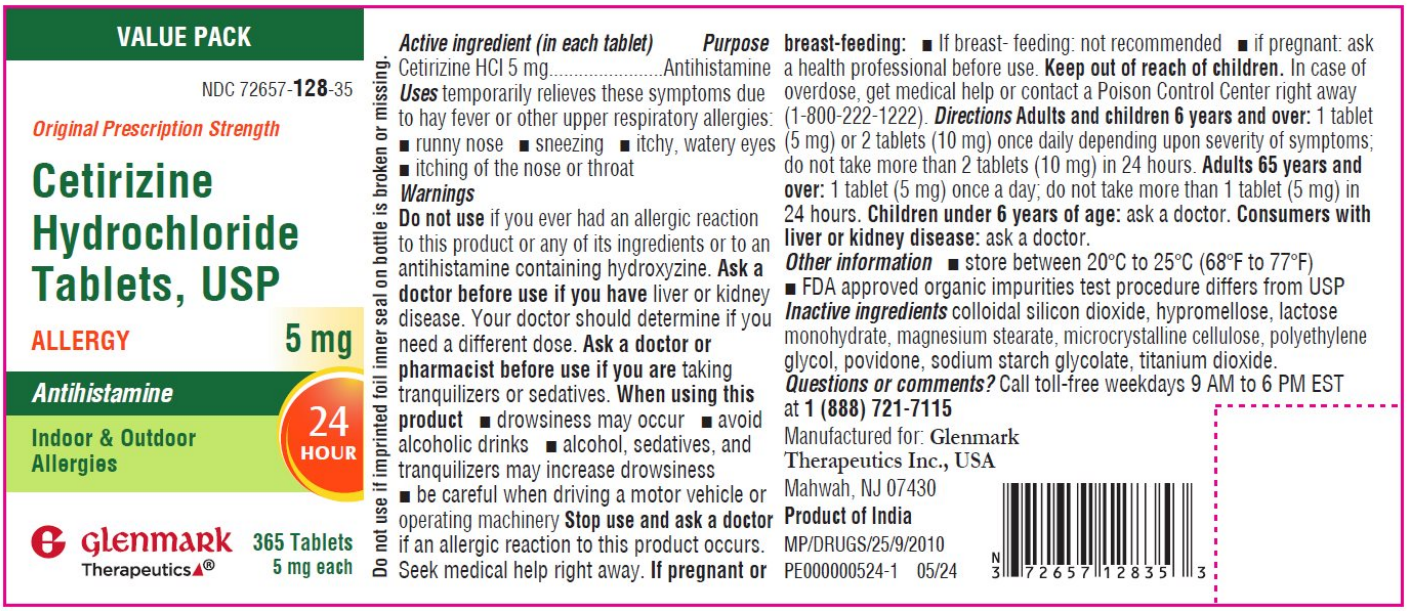
10 mg - 365 Tablets



Package/Label Principal Display Panel

NDC 72657-128-35

5 mg- 365 Tablets



Principal Display Panel

Carton label

NDC 72657-129-35

10 mg - 365 Tablets

Principal Display Panel

NDC 72657-128-35

5 mg - 365 Tablets

CETIRIZINE HCL

cetirizine tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72657-128
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETIRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	C;13
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72657-128-30	1 in 1 CARTON	05/13/2024	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:72657-128-45	1 in 1 CARTON	05/13/2024	
2		45 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:72657-128-60	1 in 1 CARTON	05/13/2024	
3		60 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:72657-128-70	1 in 1 CARTON	05/13/2024	
4		70 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:72657-128-90	1 in 1 CARTON	05/13/2024	
5		90 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:72657-128-08	1 in 1 CARTON	05/13/2024	
		120 in 1 BOTTLE; Type 0: Not a Combination		

6		120 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:72657-128-14	1 in 1 CARTON	05/13/2024	
7		140 in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:72657-128-15	1 in 1 CARTON	05/13/2024	
8		150 in 1 BOTTLE; Type 0: Not a Combination Product		
9	NDC:72657-128-18	1 in 1 CARTON	05/13/2024	
9		180 in 1 BOTTLE; Type 0: Not a Combination Product		
10	NDC:72657-128-24	1 in 1 CARTON	05/13/2024	
10		240 in 1 BOTTLE; Type 0: Not a Combination Product		
11	NDC:72657-128-03	1 in 1 CARTON	05/13/2024	
11		300 in 1 BOTTLE; Type 0: Not a Combination Product		
12	NDC:72657-128-35	1 in 1 CARTON	05/13/2024	
12		365 in 1 BOTTLE; Type 0: Not a Combination Product		
13	NDC:72657-128-04	1 in 1 CARTON	05/13/2024	
13		400 in 1 BOTTLE; Type 0: Not a Combination Product		
14	NDC:72657-128-81	2 in 1 CARTON	05/13/2024	
14		60 in 1 BOTTLE; Type 0: Not a Combination Product		
15	NDC:72657-128-82	2 in 1 CARTON	05/13/2024	
15		70 in 1 BOTTLE; Type 0: Not a Combination Product		
16	NDC:72657-128-84	2 in 1 CARTON	05/13/2024	
16		90 in 1 BOTTLE; Type 0: Not a Combination Product		
17	NDC:72657-128-86	2 in 1 CARTON	05/13/2024	
17		120 in 1 BOTTLE; Type 0: Not a Combination Product		
18	NDC:72657-128-41	1 in 1 CARTON	05/13/2024	
18		14 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	ANDA078427	05/13/2024	

CETIRIZINE HCL

cetirizine tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72657-129
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETIRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE	**Score**	no score
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	C;17
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72657-129-30	1 in 1 CARTON	05/13/2024	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:72657-129-45	1 in 1 CARTON	05/13/2024	
2		45 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:72657-129-60	1 in 1 CARTON	05/13/2024	
3		60 in 1 BOTTLE; Type 0: Not a Combination Product		

4	NDC:72657-129-70	1 in 1 CARTON	05/13/2024	
4		70 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:72657-129-90	1 in 1 CARTON	05/13/2024	
5		90 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:72657-129-08	1 in 1 CARTON	05/13/2024	
6		120 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:72657-129-14	1 in 1 CARTON	05/13/2024	
7		140 in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:72657-129-15	1 in 1 CARTON	05/13/2024	
8		150 in 1 BOTTLE; Type 0: Not a Combination Product		
9	NDC:72657-129-18	1 in 1 CARTON	05/13/2024	
9		180 in 1 BOTTLE; Type 0: Not a Combination Product		
10	NDC:72657-129-24	1 in 1 CARTON	05/13/2024	
10		240 in 1 BOTTLE; Type 0: Not a Combination Product		
11	NDC:72657-129-03	1 in 1 CARTON	05/13/2024	
11		300 in 1 BOTTLE; Type 0: Not a Combination Product		
12	NDC:72657-129-35	1 in 1 CARTON	05/13/2024	
12		365 in 1 BOTTLE; Type 0: Not a Combination Product		
13	NDC:72657-129-04	1 in 1 CARTON	05/13/2024	
13		400 in 1 BOTTLE; Type 0: Not a Combination Product		
14	NDC:72657-129-81	2 in 1 CARTON	05/13/2024	
14		60 in 1 BOTTLE; Type 0: Not a Combination Product		
15	NDC:72657-129-82	2 in 1 CARTON	05/13/2024	
15		70 in 1 BOTTLE; Type 0: Not a Combination Product		
16	NDC:72657-129-84	2 in 1 CARTON	05/13/2024	
16		90 in 1 BOTTLE; Type 0: Not a Combination Product		
17	NDC:72657-129-86	2 in 1 CARTON	05/13/2024	
17		120 in 1 BOTTLE; Type 0: Not a Combination Product		
18	NDC:72657-129-41	1 in 1 CARTON	04/03/2025	
18		14 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	ANDA078427	05/13/2024	

CETIRIZINE HCL

cetirizine kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72657-130

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72657-130-05	1 in 1 PACKAGE; Type 0: Not a Combination Product	05/13/2024	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	60
Part 2	1 BOTTLE	90

Part 1 of 2

CETIRIZINE HCL

cetirizine tablet

Product Information

Item Code (Source)	NDC:72657-128
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETIRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	C;13
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
1		60 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	ANDA078427	05/13/2024	

Part 2 of 2

CETIRIZINE HCL

cetirizine tablet

Product Information

Item Code (Source)	NDC:72657-128
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETIRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	WHITE	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	C;13
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		1 in 1 CARTON		
1		90 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	ANDA078427	05/13/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078427	05/13/2024	

CETIRIZINE HCL

cetirizine kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72657-131

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72657-131-89	1 in 1 PACKAGE; Type 0: Not a Combination Product	05/13/2024	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	60
Part 2	1 BOTTLE	90

Part 1 of 2

CETIRIZINE HCL

cetirizine tablet

Product Information

Item Code (Source)	NDC:72657-129
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETIRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE	**Score**	no score
Shape	ROUND	**Size**	8mm

Flavor		**Imprint Code**	C;17
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
1		60 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	ANDA078427	05/13/2024	

Part 2 of 2

CETIRIZINE HCL

cetirizine tablet

Product Information

Item Code (Source)	NDC:72657-129
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CETIRIZINE HYDROCHLORIDE (UNII: 64O047KTOA) (CETIRIZINE - UNII:YO7261ME24)	CETIRIZINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE K30 (UNII: U725QWY32X)	
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Product Characteristics			
Color	WHITE	**Score**	no score
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	C;17
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
1		90 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	ANDA078427	05/13/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078427	05/13/2024	

Labeler - GLENMARK THERAPEUTICS INC., USA (969085666)

Establishment

Name	Address	ID/FEI	Business Operations
Glenmark Pharmaceuticals Limited		862603186	ANALYSIS(72657-128, 72657-129, 72657-130, 72657-131) , MANUFACTURE(72657-128, 72657-129, 72657-130, 72657-131)

Revised: 4/2025 GLENMARK THERAPEUTICS INC., USA