FAMOTIDINE- famotidine tablet, film coated
GLENMARK THERAPEUTICS INC., USA

Famotidine Tablets

Drug Facts

Active ingredient (in each tablet)

Famotidine, USP 10 mg and 20 mg

Purpose

Acid reducer

Uses

- relieves heartburn associated with acid indigestion and sour stomach
- prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain food and beverages

Warnings

Allergy alert

Do not use if you are allergic to famotidine or other acid reducers

Do not use

- if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
- with other acid reducers

Ask a doctor before use if you have

- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with **lightheadedness, sweating, or dizziness**
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent **chest pain**
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain
- kidney disease

Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs.

Stop use and ask a doctor if

- your heartburn continues or worsens
- you need to take this product for more than 14 days

If pregnant or breast-feeding, 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.

Directions

- adults and children 12 years and over:
    - to **relieve** symptoms, swallow 1 tablet with a glass of water. Do not chew.
    - to **prevent** symptoms, swallow 1 tablet (of 10 mg) with a glass of water at any time from **15 to 60 minutes before** eating food or drinking beverages that cause heartburn
    - to **prevent** symptoms, swallow 1 tablet (of 20 mg) with a glass of water at any time from **10 to 60 minutes before** eating food or drinking beverages that cause heartburn
    - **before** eating food or drinking beverages that cause heartburn
    - do not use more than 2 tablets in 24 hours
- children under 12 years: ask a doctor

Other information

- read the directions and warnings before use
- keep the carton. It contains important information.
- store at 20°C to 25°C (68°F to 77°F)
- protect from moisture

Inactive ingredients

Hydroxypropyl Cellulose, Hypromellose, , Macrogol, Magnesium stearate, Microcrystalline Cellulose, Pre-gelatinized Starch, Sodium Starch glycolate, Talc, Triacetin, Titanium dioxide

Questions or comments?

Call weekdays 9 AM to 6 PM EST at **1 (888) 721-7115.**

Do not use if printed foil seal on bottle is broken or missing.

JUST ONE TABLET prevents and relieves heartburn due to acid indigestion brought on by eating and drinking certain foods and beverages.

TIPS FOR MANAGING HEARTBURN

 Do not lie flat or bend over after eating Do not wear tight-fitting clothing around the stomach

 Do not eat before bedtime Raise the head of your bed Avoid heartburn-causing foods such as rich, spicy, fatty or fried foods, chocolate, caffeine, alcohol, and certain fruits and vegetables Eat slowly and avoid big meals If overweight, lose weight Quit smoking

Distributed by: Glenmark Therapeutics Inc., USA
Elmwood Park, NJ 07407
Made in India
M.L. No.: 02/SKL/AP/2015/F/R

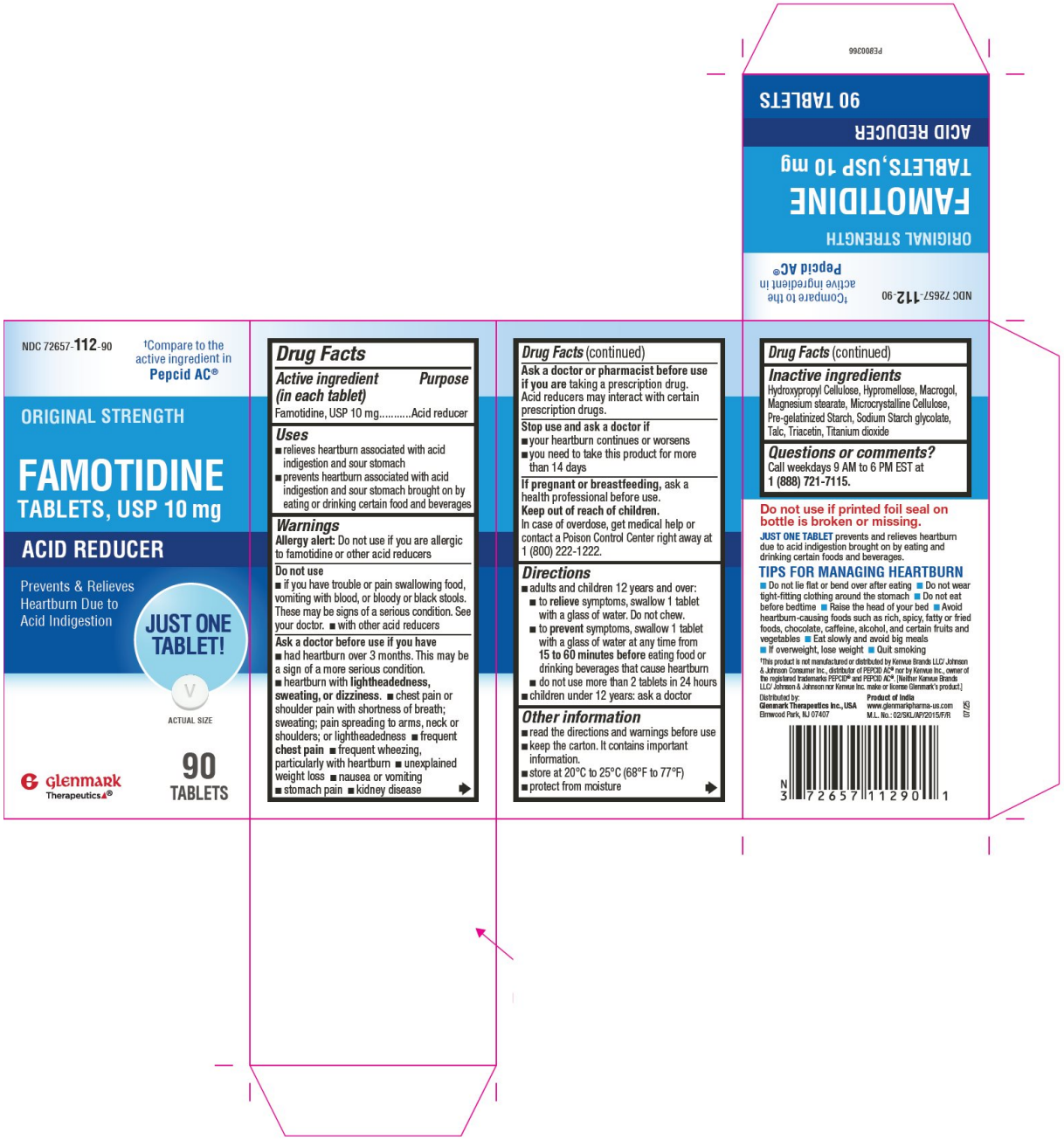
Revision: 07/25

Principal Display Panel

NDC 72657-112-90

Famotidine Tablets, USP 10mg

90 Tablets

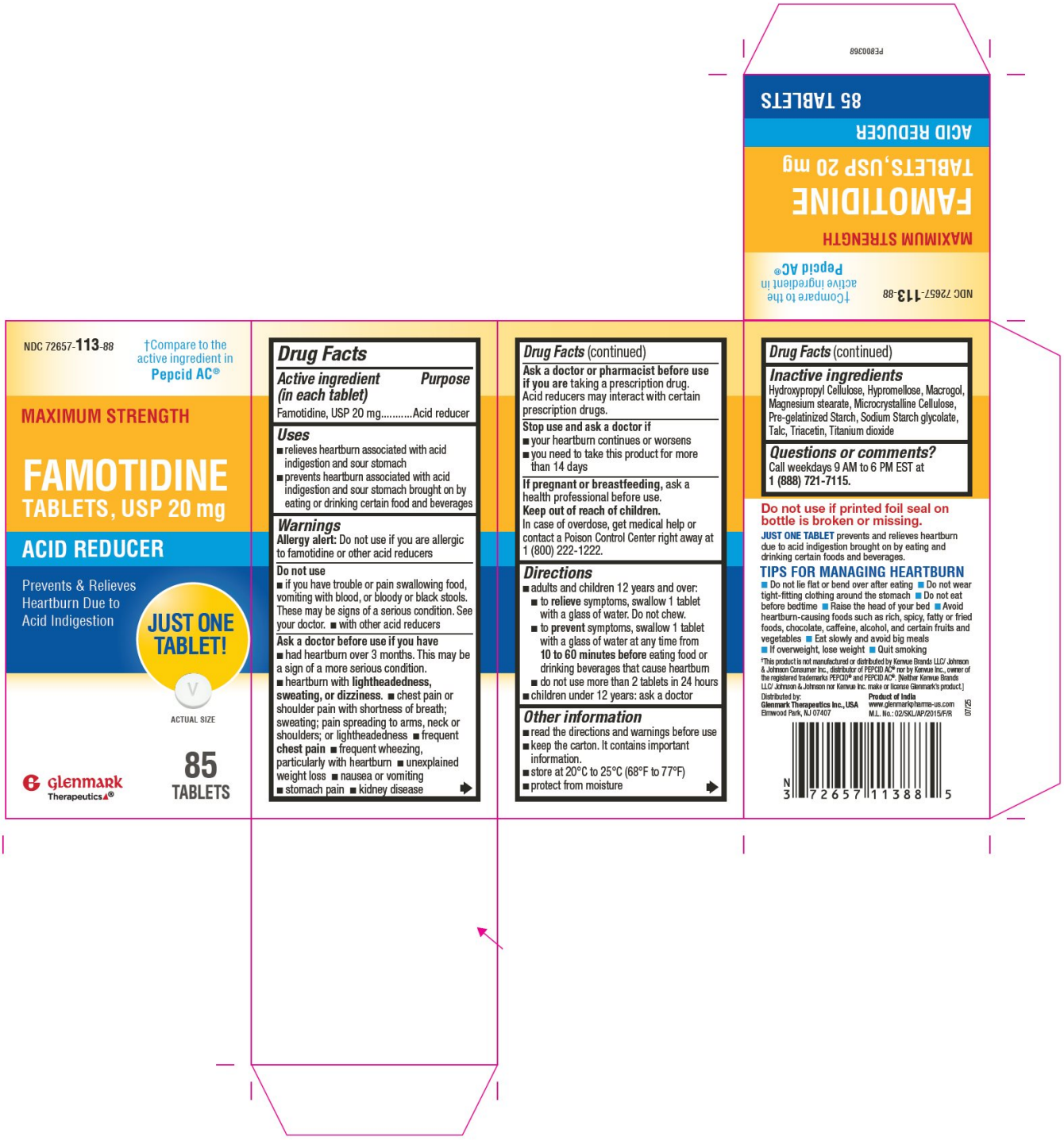


Principal Display Panel

NDC 72657-113-88

Famotidine Tablets, USP 20mg

85 Tablets

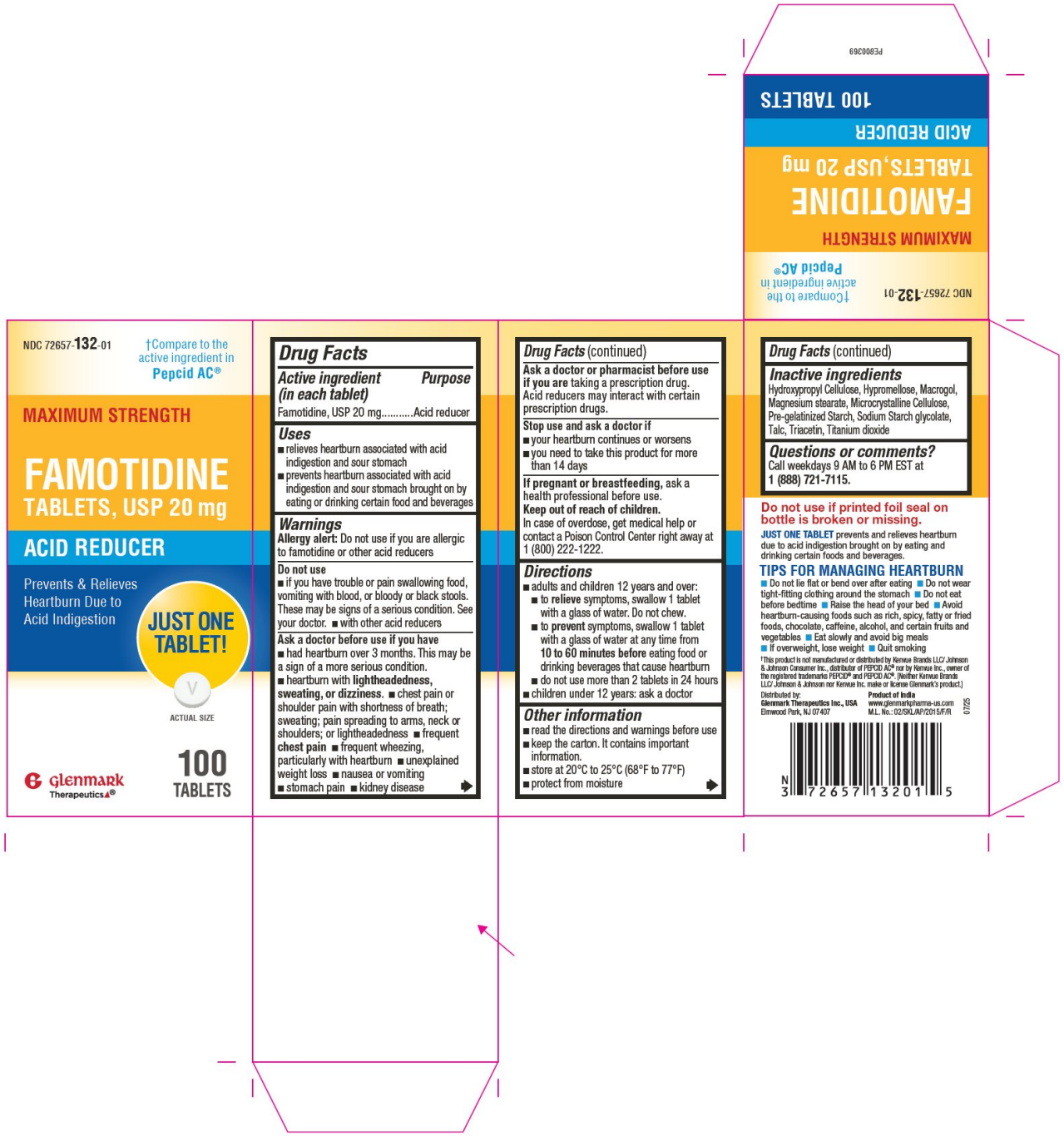


Principal Display Panel

NDC 72657-132-01

Famotidine Tablets, USP 20mg

100 Tablets



FAMOTIDINE

famotidine tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72657-112
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
FAMOTIDINE (UNII: 5QZO15J2Z8) (FAMOTIDINE - UNII:5QZO15J2Z8)	FAMOTIDINE	10 mg

Inactive Ingredients	
Ingredient Name	**Strength**
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
HYDROXYPROPYL CELLULOSE (110000 WAMW) (UNII: 5Y0974F5PW)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics			
Color	WHITE (white to off-white)	**Score**	no score
Shape	ROUND	**Size**	5mm
Flavor		**Imprint Code**	V;21
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:72657-112-90	1 in 1 CARTON	06/01/2022	
1		90 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:72657-112-20	1 in 1 CARTON	06/01/2022	
2		200 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	ANDA215822	06/01/2022	

FAMOTIDINE

famotidine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72657-113
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FAMOTIDINE (UNII: 5QZO15J2Z8) (FAMOTIDINE - UNII:5QZO15J2Z8)	FAMOTIDINE	20 mg

Inactive Ingredients

Ingredient Name	Strength
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
HYDROXYPROPYL CELLULOSE (110000 WAMW) (UNII: 5Y0974F5PW)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	WHITE (white to off-white)	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	V;15
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72657-113-88	1 in 1 CARTON	06/01/2022	
1		85 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:72657-113-20	1 in 1 CARTON	06/01/2022	
2		200 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	ANDA215822	06/01/2022	

FAMOTIDINE

famotidine tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72657-132
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
FAMOTIDINE (UNII: 5QZO15J2Z8) (FAMOTIDINE - UNII:5QZO15J2Z8)	FAMOTIDINE	20 mg

Inactive Ingredients	
Ingredient Name	**Strength**
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
HYDROXYPROPYL CELLULOSE (110000 WAMW) (UNII: 5Y0974F5PW)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics			
Color	WHITE (white to off-white)	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	V;15
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:72657-132-01	1 in 1 CARTON	10/08/2024	
1		100 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	ANDA215822	10/08/2024	

Labeler - GLENMARK THERAPEUTICS INC., USA (969085666)

Establishment

Name	Address	ID/FEI	Business Operations
VKT Pharma Private Limited		871408062	MANUFACTURE(72657-112, 72657-113, 72657-132) , ANALYSIS(72657-112, 72657-113, 72657-132)

Revised: 1/2026 GLENMARK THERAPEUTICS INC., USA