

FAMOTIDINE- famotidine tablet, film coated
VKT Pharma Private Limited

Famotidine tablet, film coated

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
 - 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° - 25°C (68° - 77°F)
- protect from moisture
- compares to the active ingredient in Zantac 360

Inactive ingredients

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

Questions or comments?

1 844-387-1231 (toll-free)

Manufactured by:

VKT Pharma Private Limited

Srikakulam, India-532 409,

M.L. No.: 02/SKL/AP/2015/F/R

Repackaged by:



Granules USA Inc,

35 Waterview Blvd, 3rd Floor
Parsippany NJ 07054 USA.

Revision: 08/2022

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Famotidine Tablets USP 10mg - NDC 71821-012-08 -Container Label

VKT PHARMA PRIVATE LIMITED		
Product name : Famotidine tablets, USP 10 mg.		 XXXXXXXXXX NDC No.:
Batch No. : XXXXXXXXXXXX	Tare weight : 0.000 Kg	
Mfg. date : MM/YYYY	Net weight : 0.000 Kg	
Exp. date : MM/YYYY	Gross weight : 0.000 Kg	
NDC Number : XXXX-XXX-XXX	Container No. : 00 of 00	
Retest date : DD/MM/YYYY (Tablets Shall be packed before the retest date)		
Storage condition : Store at 20° to 25°C (68° to 77°F).Each Tablet contains, Famotidine USP 10 mg.		
Mfg. Lic. No.: 02/SKL/AP/2015/F/G		
Manufactured by VKT Pharma Private Limited Survey No. 21 to 27, Derasam Village, Ranasthalam Mandal, Srikakulam District-532409. Andhra Pradesh, India.		
Country of Origin : INDIA		

Famotidine Tablets USP 10mg - NDC 71821-012-08 -Pouch Label

FAMOTIDINE TABLETS, USP 10 mg

Store at 20° to 25°C (68° to 77°F).
Each Tablet contains, Famotidine USP 10 mg.

Manufactured By-
VKT Pharma Private Limited,
Srikakulam, India- 532 409.
ML No.: 02/SKL/AP/2015/F/R

NDC No.:



Batch No.: XXXXXXXXXXXX

Number of Units : XXXXXXXX No's

Mfg. Date: DD/MM/YY

Tare Weight : XXX.XXX Kg

Exp. Date: DD/MM/YY

Net Weight : XXX.XXX Kg

Country of Origin : INDIA

Gross Weight : XXX.XXX Kg

Retest date : DD/MM/YY

NOTE: Tablets shall be packed before retest date.

Container No.: 00 of 00

Famotidine Tablets USP 20mg - NDC 71821-010-12 -Container Label

VKT PHARMA PRIVATE LIMITED



Product name : Famotidine tablets, USP 20 mg.

Batch No. : XXXXXXXXXXX

Tare weight : 0.000 Kg

Mfg. date : MM/YYYY

Net weight : 0.000 Kg

Exp. date : MM/YYYY

Gross weight : 0.000 Kg

NDC Number : XXXX-XXX-XXX

Container No. : 00 of 00

Retest date : DD/MM/YYYY
(Tablets Shall be packed before the retest date)



Storage condition : Store at 20° to 25°C (68° to 77°F). Each Tablet contains, Famotidine USP 20 mg.

Mfg. Lic. No.: 02/SKL/AP/2015/F/G

Manufactured by
VKT Pharma Private Limited
Survey No. 21 to 27, Derasam Village, Ranastharam Mandal, Srikakulam District-532409. Andhra Pradesh,
India.

Country of Origin : INDIA

Famotidine Tablets USP 20mg - NDC 71821-010-12 -Pouch Label

FAMOTIDINE TABLETS, USP 20 mg

Store at 20° to 25°C (68° to 77°F).
Each Tablet contains, Famotidine USP 20 mg.

Manufactured By-
VKT Pharma Private Limited,
Srikakulam, India- 532 409.
ML No.: 02/SKL/AP/2015/F/R

NDC No.:



Batch No.: XXXXXXXXXXXXX

Number of Units : XXXXXXXX No's

Mfg. Date: DD/MM/YY

Tare Weight : XXX.XXX Kg

Exp. Date: DD/MM/YY

Net Weight : XXX.XXX Kg

Country of Origin : INDIA

Gross Weight : XXX.XXX Kg

Retest date : DD/MM/YY

NOTE: Tablets shall be packed before retest date.

Container No.: 00 of 00

FAMOTIDINE

famotidine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71821-012
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)	

TRIA CETIN (UNII: XHX3C3X673)

POLYETHYLENE GLYCOL 4000 (UNII: 4R4HF16D95)

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:71821-012-08	288461 in 1 BAG; Type 0: Not a Combination Product	09/07/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA215822	01/28/2022	

FAMOTIDINE

famotidine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71821-010
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FAMOTIDINE (UNII: 5QZ015J2Z8) (FAMOTIDINE - UNII:5QZ015J2Z8)	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:71821-010-12	144230 in 1 BAG; Type 0: Not a Combination Product	09/07/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA215822	01/28/2022	

Labeler - VKT Pharma Private Limited (871408062)

Registrant - VKT Pharma Private Limited (871408062)

Establishment

Name	Address	ID/FEI	Business Operations
VKT Pharma Private Limited		871408062	manufacture(71821-012, 71821-010)

Revised: 1/2024

VKT Pharma Private Limited