VIATREXX-ENZYME PLUS- amylase, cellulase, lactase, lipase, maltase, protease, sucrase spray

VIATREXX BIO INCORPORATED

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

Enzyme +

Active Ingredients

Amylase (6X, 30K & 200K), Cellulase (6X, 30K & 200K), Lactase (6X, 30K & 200K), Lipase (6X, 30K & 200K), Maltase (6X, 30K & 200K), Protease (6X, 30K & 200K), Sucrase (6X, 30K & 200K)

Purpose

Amylase Enzyme for Starches
Cellulase Enzyme for Cellulose
Lactase Enzyme for Lactose and dairy
Lipase Enzyme for Fats
Maltase Enzyme for Maltose
Protease Enzyme for Proteins
Sucrase Enzyme for Sugars

Description

Viatrexx-Enzyme + is a homeopathic product composed of physiological (low dose and low low dose) natural micro nutrients. These micro particles are designed to nourish the system.

Uses

To support healthy digestion.

Warnings

Stop use and ask a health care practitioner if symptoms persist for more than five days or worsen. If pregnant or breastfeeding, ask a health care practitioner before use.

Dosage

1-3 spray(s); 1-3 time(s) per day or as recommended by your health care practitioner.

Keep this and all medicines out of reach of children.

Inactive Ingredients

20% Alcohol and 80% Water

Other Information

Normal storage use.

Do not use if tamper-evident seal is broken or removed.

Product availability

Product may be acquired in 0.5, 30, 50, 100, 250 mL bottles.

References upon request

To report SUSPECTED ADVERSE REACTIONS, contact the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

Distributed by

Viatrexx Bio Incorporated

Newark, DE, USA, 19713

Manufactured by

8046255 Canada Inc Beloeil, Qc, J3G 6S3

Date of last revision March 2019

For Questions and comments Info@Viatrexx.com www.Viatrexx.com

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC: 63776-142-11 Item: VPC0045

Viatrexx Bio Incorporated

Viatrexx- Enzyme + Box of 1 X 0.5 mL ampule

For Oral and Topical Use

Expiry date: Lot #:

Manufactured for:

Viatrexx Bio Incorporated Newark, DE, USA, 19713

www.Viatrexx.com

Ingredients, homeopathic

See insert or www.viatrexx.com

Inactives: Alcohol 20%, Water 80%

NDC: 63776-142-14 Item: VPC0045

Viatrexx Bio Incorporated

Viatrexx-Enzyme + Box of 1 X 30 mL spray bottle For Oral and Topical Use

Expiry date: Lot #:

Manufactured for:

Viatrexx Bio Incorporated Newark, DE, USA, 19713

www.Viatrexx.com

Ingredients, homeopathic

See insert or www.viatrexx.com

Inactives: Alcohol 20%, Water 80%

NDC: 63776-142-15 Item: VPC0045

Viatrexx Bio Incorporated

Viatrexx-Enzyme +
Box of 1 X 50 mL spray bottle
For Oral and Topical Use

Expiry date: Lot #:

Manufactured for:

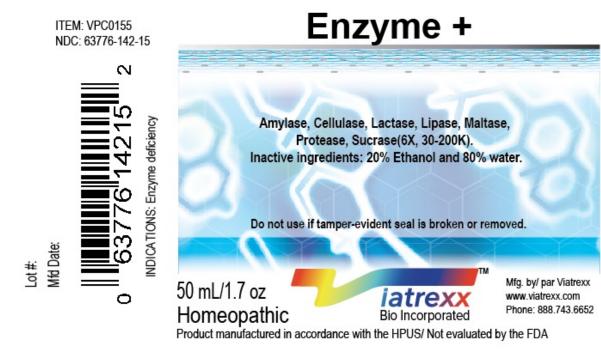
Viatrexx Bio Incorporated Newark, DE, USA, 19713

www.Viatrexx.com

Ingredients, homeopathic

See insert or www.viatrexx.com

Inactives: Alcohol 20%, Water 80%



Directions: 1-5 spray/s: 1-3 time/s per day or as recommended by your health practitioner

Warnings:
Stop use and ask a
health care practitioner
if symptoms persist for
more than 5 days or
worsen. If pregnant or
breadt-feeding, ask a
health care practitioner
before use. Keep this
and all medicines out
of reach of children.

Normal storage use.

NDC: 63776-142-16 Item: VPC0045

Viatrexx Bio Incorporated

Viatrexx-Enzyme +
Box of 1 X 100 mL bottle
For Oral and Topical Use

Expiry date: Lot #:

Manufactured for:

Viatrexx Bio Incorporated Newark, DE, USA, 19713

www.Viatrexx.com

Ingredients, homeopathic

See insert or www.viatrexx.com

Inactives: Alcohol 20%, Water 80%

NDC: 63776-142-17 Item: VPC0045

Viatrexx Bio Incorporated

Viatrexx-Enzyme +
Box of 1 X 250 mL bottle
For Oral and Topical Use

Expiry date: Lot #:

Manufactured for:

Viatrexx Bio Incorporated Newark, DE, USA, 19713

www.Viatrexx.com

Ingredients, homeopathic

See insert or www.viatrexx.com

Inactives: Alcohol 20%, Water 80%

VIATREXX-ENZYME PLUS

amylase, cellulase, lactase, lipase, maltase, protease, sucrase spray

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63776-142		
Route of Administration	ORAL, TOPICAL				

Active Ingredient/Active Moiety					
Ingredient Name	Basis of Strength	Strength			
Pancreatic Alpha-Amylase (UNII: CIK15T34RB) (Pancreatic Alpha-Amylase - UNII:CIK15T34RB)	Pancreatic Alpha-Amylase	30 [kp_C] in 1 mL			
Cellulase (Trichoderma Longibrachiatum) (UNII: 7Q170212NX) (Cellulase (Trichoderma Longibrachiatum) - UNII:7Q170212NX)	Cellulase (Trichoderma Longibrachiatum)	30 [kp_C] in 1 mL			
Lactase (UNII: 37515NWH9U) (Lactase - UNII:37515NWH9U)	Lactase	30 [kp_C] in 1 mL			
Pancreatic Triacylglycerol Lipase (UNII: THEA1III4L) (Pancreatic Triacylglycerol Lipase - UNII:THEA1III4L)	Pancreatic Triacylglycerol Lipase	30 [kp_C] in 1 mL			
Lysosomal Alpha-Glucosidase (UNII: S0FLU182ZW) (Lysosomal Alpha-Glucosidase - UNII:S0FLU182ZW)	Lysosomal Alpha- Glucosidase	30 [kp_C] in 1 mL			
Pancrelipase Protease (UNII: 3560D81V50) (Pancrelipase Protease - UNII:3560D81V50)	Pancrelipase Protease	30 [kp_C] in 1 mL			
Sacrosidase (UNII: 8A7F670F2Y) (Sacrosidase - UNII:8A7F670F2Y)	Sacrosidase	30 [kp_C] in 1 mL			

Inactive Ingredients			
Ingredient Name	Strength		
Water (UNII: 059QF0KO0R)			
Alcohol (UNII: 3K9958V90M)			

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:63776-142- 11	1 in 1 BOX	07/05/2019			
1		0.5 mL in 1 AMPULE; Type 0: Not a Combination Product				
2	NDC:63776-142- 14	1 in 1 BOX	07/05/2019			
2		30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product				

3	NDC:63776-142- 15	1 in 1 BOX	07/05/2019	
3		50 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		
4	4 NDC:63776-142- 16 1 in 1 BOX		07/05/2019	
4	100 mL in 1 BOTTLE; Type 0: Not a Combination Product			
5	5 NDC:63776-142- 17 1 in 1 BOX		07/05/2019	
5		250 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	
unapproved homeopathic		03/29/2019		

Labeler - VIATREXX BIO INCORPORATED (078419880)

Establishment					
Name	Address		Business Operations		
8046255 Canada Inc		200651455	api manufacture (63776-142) , label (63776-142) , manufacture (63776-142) , pack (63776-142)		

Establishment				
Name	Address	ID/FEI	Business Operations	
Les Importations Herbasante Inc		243254612	manufacture(63776-142)	

Revised: 3/2019 VIATREXX BIO INCORPORATED