ESOMEPRAZOLE MAGNESIUM- esomeprazole magnesium capsule, delayed release Amneal Pharmaceuticals NY LLC

Amneal Pharmaceuticals

Esomeprazole Magnesium Delayed-Release Capsules, USP 20 mg/Acid Reducer (OTC)

Drug Facts

Active ingredient (in each capsule)	Purpose
Esomeprazole 20 mg	Acid reducer
(*Each delayed-release capsule corresponds to 22.3 trihydrate)	mg esomeprazole magnesium

Uses

- treats frequent heartburn (occurs <u>2 or more</u> days a week)
- not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

Warnings

Allergy alert:

- Do not use if you are allergic to esomeprazole
- Esomeprazole may cause severe skin reactions. Symptoms may include:
- skin reddening
- blisters
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

Do not use if you have

- trouble or pain swallowing food, vomiting with blood, or bloody or black stools
- 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

These may be signs of a serious condition. See your doctor.

Ask a doctor before use if you have

- had heartburn over 3 months. This may be a sign of a more serious condition.
- frequent wheezing, particularly with heartburn
- unexplained weight loss

- nausea or vomiting
- stomach pain

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
- you need to take more than 1 course of treatment every 4 months
- you get diarrhea
- you develop a rash or joint pain

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of the reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- adults 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- may take 1 to 4 days for full effect

14-Day Course of Treatment

- swallow 1 capsule with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 capsule a day
- swallow whole. Do not crush or chew capsules.
- do not use for more than 14 days unless directed by your doctor

Repeated 14-Day Courses (if needed)

- you may repeat a 14-day course every 4 months
- do not take for more than 14 days or more often than every 4 months unless directed by a doctor
- children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.

Other Information

- read the directions and warnings before use
- keep the carton. It contains important information.
- store at 20° to 25°C (68° to 77°F)
- Tamper Evident: Do not use if printed safety seal under cap or band around the center of each capsule is broken or missing.

Inactive ingredients

gelatin, hypromellose, magnesium stearate, methacrylic acid copolymer dispersion type C, mono-and di-glycerides, polysorbate 80, sugar sphere (contains- sucrose, corn starch and purified water), sodium lauryl sulphate, talc, triethyl citrate and titanium dioxide.

Each capsule is imprinted with blue pharmaceutical ink which contains butyl alcohol, dehydrated alcohol, FD & C Blue # 2 aluminum lake, isopropyl alcohol, propylene glycol, shellac, strong ammonia solution and having one circular line which contains FD & C Blue No. 2 aluminum lake, gelatin and polysorbate 80.

Questions or comments?

Call toll-free 1-877-835-5472

Mon – Fri 9AM – 5PM EST.

Made in India For most recent product information, visit www.amneal.com

Principal Display Panel

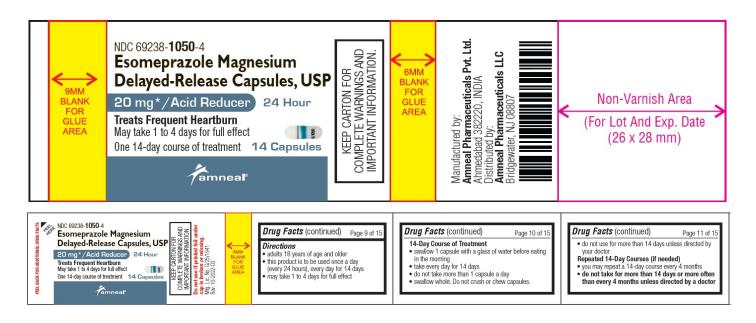
NDC 69238-1050-4

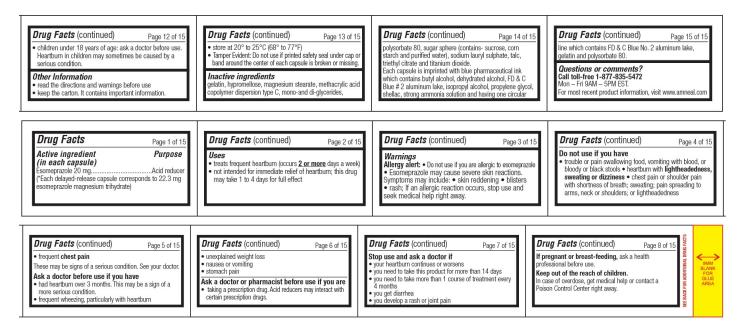
Esomeprazole Magnesium Delayed-Release Capsules, USP/Acid Reducer (OTC)

20 mg

14 Capsules (Container Label)

Amneal Pharmaceuticals LLC





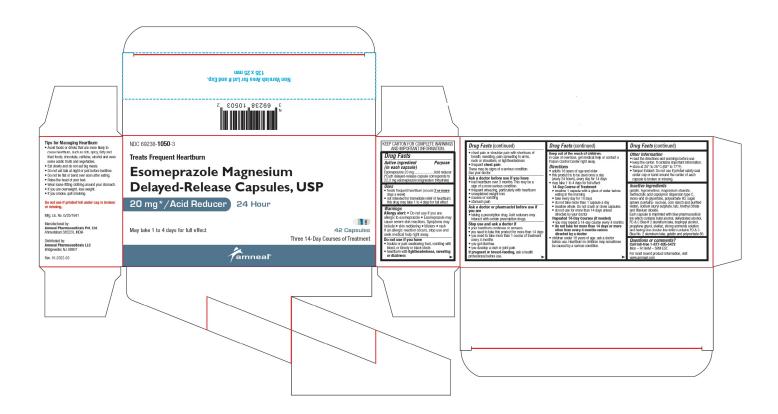
NDC 69238-1050-3

Esomeprazole Magnesium Delayed-Release Capsules, USP /Acid Reducer (OTC)

20 mg

42 Capsules (Carton Pack)

Amneal Pharmaceuticals LLC



ESOMEPRAZOLE MAGNESIUM

esomeprazole magnesium capsule, delayed release

Product Infor	mation							
Product Type		HUMAN OTC DI	RUG	ltom (ode (Source	• •	NDC:6923	8-1050
	- t			item	m Code (Source) NDC:692			0 1050
Route of Admini	stration	ORAL						
Active Ingredi	ent/Active	Moietv						
		-				Bas	sis of	.
Ingredient Name Strength								Strength
ESOMEPRAZOLE M UNII:N3PA6559FT)	IAGNESIUM (U	NII: R6DXU4WAY	9) (ESOMEI	PRAZOLE	-	ESOMEPF	RAZOLE	20 mg
UNII.INSPA0559FT)								
Inactive Ingre	dients							
		Ingredie	ent Name	3				Strength
ALCOHOL (UNII: 3K	9958V90M)							
AMMONIA (UNII: 51	38Q19F1X)							
BUTYL ALCOHOL (UNII: 8PJ61P6T9	53)						
CAPRYLIC/CAPRIC	MONO/DI-GLY	CERIDES (UNII:	: U72Q2I8C	85)				
FD&C BLUE NO. 2	(UNII: L06K8R7	DQK)						
GELATIN (UNII: 2G8	6QN327L)							
HYPROMELLOSE,	UNSPECIFIED	(UNII: 3NXW29V3	3WO)					
ISOPROPYL ALCOHOL (UNII: ND2M416302)								
MAGNESIUM STEARATE (UNII: 70097M6I30)								
METHACRYLIC ACI			POLYMER	(UNII: N	X76LV5T8J)			
POLYSORBATE 80								
PROPYLENE GLYC		Q167V3)						
SHELLAC (UNII: 46N	-							
SODIUM LAURYL S								
STARCH, CORN (UI		J)						
SUCROSE (UNII: C1								
TALC (UNII: 7SEV7J4 TITANIUM DIOXIDE		(םוכי						
TRIETHYL CITRATE	•							
WATER (UNII: 059Q								
	i oncoon,							
Product Chara	cteristics							
Color	white	:	Score			no sco	ore	
Shape	CAPSUL	E	Size		14mm			
Flavor		Imprint Code AMNEAL1050						
Contains								
Packaging						C1		
# Item Code	Pa	ckage Descr	iption		Marketing Date			ting End ate
1 NDC:69238-	2 in 1 BLISTER	R PACK		()6/05/2019			
1050-9					,,,			

6	NDC:09238-1 in 1 BLISTER PACKNDC:69238-14 in 1 BOTTLE; Type 0: Not a Combination		06/05/2019	
э 6	1050-4 NDC:69238-	Product	06/05/2010	
5	NDC:69238-	3 in 1 CARTON 14 in 1 BOTTLE; Type 0: Not a Combination	06/05/2019	
4	NDC:69238- 1050-4 NDC:69238-	Product		
4	NDC:69238- 1050-2 NDC:69238-	2 in 1 CARTON 14 in 1 BOTTLE; Type 0: Not a Combination	06/05/2019	
3	NDC:69238- 1050-4	14 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:69238- 1050-5	1 in 1 CARTON	06/05/2019	
2	NDC:69238- 1050-4	14 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69238- 1050-8	3 in 1 BLISTER PACK	06/05/2019	
1	NDC:69238- 1050-4	14 in 1 BOTTLE; Type 0: Not a Combination Product		

Labeler - Amneal Pharmaceuticals NY LLC (123797875)

Establishment

Name	Address	ID/FEI	Business Operations
Amneal Pharmaceuticals Private Limited		915076126	analysis(69238-1050) , label(69238-1050) , manufacture(69238- 1050) , pack(69238-1050)

Revised: 12/2023

Amneal Pharmaceuticals NY LLC