ESOMEPRAZOLE MAGNESIUM DELAYED-RELEASE CAPSULES, 20 MG esomeprazole magnesium delayed-release capsules, 20 mg capsule, delayed release ESOMEPRAZOLE MAGNESIUM DELAYED-RELEASE 20 MG MINI - esomeprazole magnesium delayed-release 20 mg mini capsule, delayed release MARKSANS PHARMA LIMITED

Esomeprazole Magnesium Delayed-Release Capsules USP 20 mg

Active ingredient (in each capsule)

Esomeprazole 20 mg

(Each delayed-release capsule corresponds to 22.3 mg esomeprazole magnesium trihydrate)

Purpose

Acid reducer

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 include:
- o skin reddening
- o blisters
- o rash

If an allergic reaction occurs, stop use and seek medical attention 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 reach of children

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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 20-25°C (68-77°F)

Inactive ingredients

Esomeprazole Magnesium Delayed-Release Capsules USP 20 mg

Inactive ingredients black iron oxide, eudragit, FD&C Blue 1, FD&C Red 3, ferric oxide yellow, gelatin, glyceryl monostearate, hydroxypropyl cellulose, hypromellose, magnesium stearate, polysorbate 80, potassium hydroxide, shellac, simethicone, sodium lauryl sulfate, sugar spheres, talc, titanium dioxide, triethyl citrate.

Esomeprazole Magnesium Delayed-Release Capsules 20 mg (Mini Capsules)

Inactive ingredients black iron oxide, corn starch, D&C red 27 aluminum lake, eudragit, FD&C blue 1, FD&C red 3, ferric oxide yellow, gelatin, glyceryl monostearate, hydroxypropyl cellulose, hypromellose, magnesium stearate, polysorbate 80, potassium hydroxide, shellac, simethicone, sodium lauryl sulfate, sucrose, talc, titanium dioxide, triethyl citrate

Questions or comments

Call 1-877-376-4271 (weekdays 9 AM to 5 PM)

Tips for Managing Heartburn

• Avoid foods or drinks that are more likely to cause heartburn, such as rich, spicy, fatty and fried foods, chocolate, caffeine, alcohol and even some acidic fruits and vegetables.

- Eat slowly and do not eat big meals.
- Do not eat late at night or just before bedtime.
- Do not lie flat or bend over soon after eating.
- Raise the head of your bed.
- Wear loose-fitting clothing around your stomach.
- If you are overweight, lose weight.
- If you smoke, quit smoking.

Manufactured for: **Time-Cap Labs, Inc.** 7 Michael Avenue, Farmingdale, NY 11735, USA

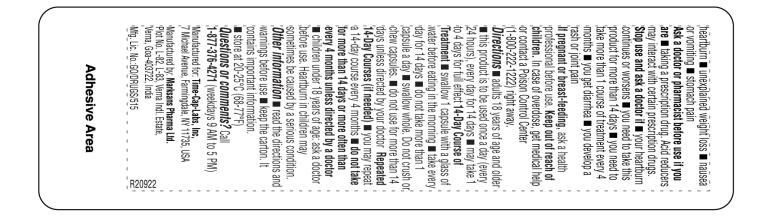
Manufactured by: Marksans Pharma Ltd. Plot No. L-82, L-83 Verna Indl. Estate Verna, Goa-403722, India

PRINCIPAL DISPLAY PANEL

NDC: 25000-075-76

Esomeprazole Magnesium Delayed-Release Capsules USP 20 mg

14 count bottle label

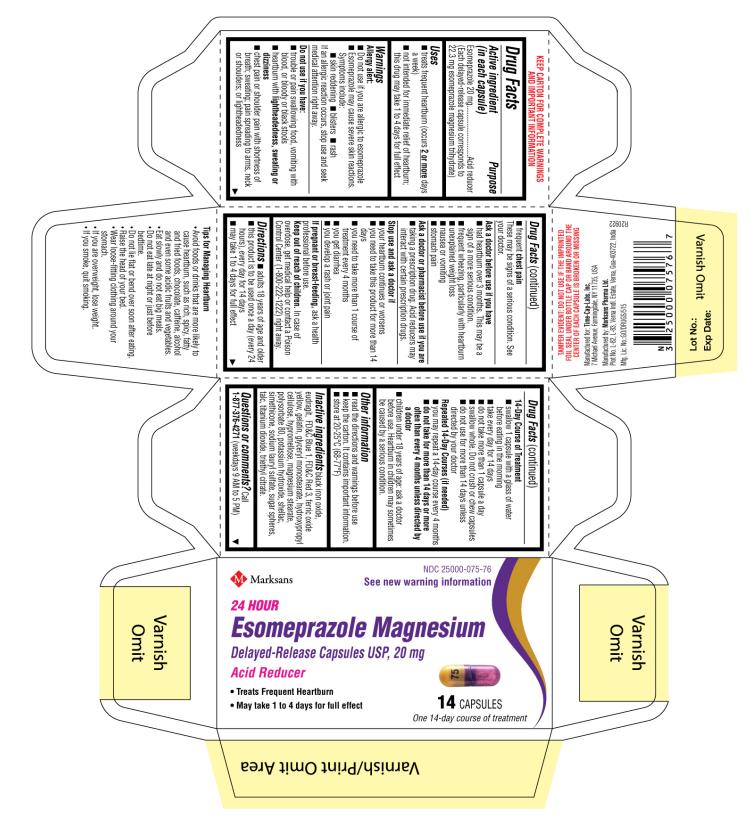




NDC: 25000-075-76

Esomeprazole Magnesium Delayed-Release Capsules USP 20 mg

14 count carton label



NDC: 25000-112-76

Esomeprazole Magnesium Delayed-Release Capsules USP 20 mg (Mini capsules) 14 count bottle label

 Repéated 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 unses directed by a doctor
children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused Mfg. Lic. No.:GO/DRUGS/515 Manufactured by: Marksans Pharma Ltd. Plot No. L-82, L-83, Verna Indl. Estate, Verna, Goa-403722, India: **Questions or comments?** Call **1-877-376-4271** (weekdays 9 AM to 5 PM) Vanufactured for: Time-Caps Labs, Inc. 7 Michael Avenue, Farmingdale, NY 11735, USA ed 3, ferric oxide yellow, gelatin, glyceryl monostearate, **(eep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center 1-800-222-1222) right away. Drug Facts (continued imethicone, sodium lauryl sulfate, sucrose, talc, titanium. tearate, polysorbate 80, potassium hydroxide, shellac, ydroxypropyl cellulose, hypromellose, magnesium **nactive ingredients** black iron oxide, corn starch V&C red 27 aluminum lake, eudragit, FD&C blue 1, FD&C, read the directions and warnings before use keep the carton. It contains important information. store at 20-25°C (68-77°F) irections oxide, triethyl citrate 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 ther information adults 18 years of age and older this product is to be used once a day (every 24 hours), every day for 14 days iore use. you develop a rash or joint pain pregnant or breast-feeding, ask a health professional you get diarrhea every 4 months **k a doctor or pharmacist before use if you are** taking a prescription drug. Acid reducers may interact nausea or vomiting by a serious condition. stomach pain with certain prescription drugs. , do not take more than 1 capsule a day I swallow whole. Do not crush or chew capsules do not use for more than 14 days unless directed ay take 1 to 4 days for full effect I-Day Course of Treatment use and ask a doctor if take every day for 14 days swallow 1 capsule with a glass of water before eating in the morning your doctor Adhesive Area R00923



NDC: 25000-112-76

Esomeprazole Magnesium Delayed-Release Capsules USP 20 mg (Mini capsules)

14 count carton label



ESOMEPRAZOLE MAGNESIUM DELAYED-RELEASE CAPSULES, 20 MG

esomeprazole magnesium delayed-release capsules, 20 mg capsule, delayed release

Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:25000-075			
Route of Administration	ORAL					

Active I	ngredi	ent/Active Moiety			
		Ingredient Name	Basis of Strength	Strengt	
Somepr JNII:N3PA6		1AGNESIUM (UNII: R6DXU4WAY9) (ESOMEPR	ESOMEPRAZ OLE	20 mg	
		dianta			
nactive	e ingre				Ctwo w w th
					Strength
		E (UNII: 8Z96QXD6UM)			
		(UNII: 60ZP39ZG8H)			
		CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6			
		RATE (UNII: 70097M6I30)	NOOH)		
		STEARATE (UNII: 2300U9XXE4)			
		IFIED (UNII: 2G86QN327L)			
		(UNII: 15FIX9V2JP)			
		(UNII: H3R47K3TBD)			
		LOW (UNII: EX43802MRT)			
		UNII: PN2ZH5LOQY)			
		V107B71O)			
		DXIDE (UNII: XM0M87F357)			
		OXIDE (UNII: WZH3C48M4T)			
		NII: 08232NY3SJ)			
		51H8M554)			
		ULFATE (UNII: 368GB5141J)			
		II: 92RU3N3Y1O)			
		D AND ETHYL ACRYLATE COPOLYMER (L	JNII: NX76LV5T8I)		
Product	t Chara	acteristics			
Color	PURPLE	(golden cap and violet transparent body ha	ving light violet to v	olet colour Score	no
	band) CAPSUL	iu)			score 14mm
Shape	CAPSULE			Size Imprint	
Flavor				Code	75
Contains	;				
Packag	ing				
# Item	Code	Package Description	Marketin Dat	-	eting End Date
1 NDC:25	000-075-	1 in 1 CARTON	09/30/2023		
. •		14 in 1 BOTTLE; Type 0: Not a Combination			

Marketing Category	Application Number or Monograph Citation ANDA217264			Marketing Start Date		Marketing End Date	
ANDA							Succ
	-			_	-	-	11
esomeprazole ma	ignesium de	elayed-release 20 mg n	піпі сар	sule, delaye	ed release	5	
Product Inform	nation						
Product Type		HUMAN OTC DRUG	ltem C	ode (Sourc	e)	NDC:25	000-112
Route of Adminis	tration	ORAL					
Active Ingredie	ent/Active	Moiety					
	Ing	redient Name				is of ngth	Strengt
	AGNESIUM (U	NII: R6DXU4WAY9) (ESOMEP	RAZOLE	-	ESOMEPRA	ZOLE	20 mg
UNII:N3PA6559FT)							
Inactive Ingred	lients						
		Ingredient Name	ł				Strength
FERROSOFERRIC O							
STARCH, CORN (UN		•					
		(UNII: ZK64F7XSTX)	/! !				
FD&C BLUE NO. 1 ((OLVO10J)			
FD&C BLUE NO. 1 (FD&C RED NO. 3 (U							
FERRIC OXIDE YELL							
GELATIN, UNSPECI	•						
GLYCERYL MONOS							
		JNSPECIFIED (UNII: 9XZ8H	6N6OH)				
HYPROMELLOSE, U							
MAGNESIUM STEAR							
POLYSORBATE 80 (
POTASSIUM HYDRO							
SHELLAC (UNII: 46N)		,					
DIMETHICONE (UNII))					
SODIUM LAURYL SU	JLFATE (UNII:	368GB5141J)					
SUCROSE (UNII: C15							
TALC (UNII: 7SEV7J4F							
TALC (UNII: 7SEV7J4F	(UNII: 15FIX9V	2JP)					
-		•					
TITANIUM DIOXIDE		•					

Color	band)			Score	score	
Shape	CAPSUL	E	Size	11mm		
Flavor				Imprint Code	112	
Contains	5					
Packag	jing					
# Item	Code	ode Package Description Mark			Marketing End Date	
1 NDC:25	000-112-	1 in 1 CARTON	03/18/2024			
1		14 in 1 BOTTLE; Type 0: Not a Combination Product				
Marke	eting I	nformation				
Mari	ceting	Application Number or Monograph Citation	Marketing Sta Date		ing End	
	egory	Citation				

Labeler - MARKSANS PHARMA LIMITED (925822975)

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	MANUFACTURE(25000-075, 25000-112)

Revised: 3/2024

MARKSANS PHARMA LIMITED