MAGNESIUM OXIDE- magnesium oxide tablet H. J. Harkins Company Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Active Ingredient

Magnesium Oxide 400 mg (241.3 mg Elemental Magnesium)

Purpose

relieves:

acid indigestion upset stomach

KEEP OUT OF REACH OF CHILDREN

Ask a doctor before use if

you have kidney disease you are taking a prescription drug (antacids may interact with certain prescription drugs) you are pregnant or breast feeding.

Do not take more than 2 tablets in a 24 hour period.

May have a laxative effect.

Keep out of reach of children.

Dosage and Administration

take one or two antacid tablets daily. Do not exceed two tablets unless directed by a physician.

Storage & Handling

Store at controlled room temperature 15° to 30°C (59° to 86°F). Tamper evident, do not use if imprinted safety seal under cap is broken or missing.

Inactive Ingredients

Croscarmellose Sodium, Microcrystalline Cellulose, Silicon Dioxide, and Stearic Acid.

Indications & Usage

Antacid

Warnings

Do not take this product if you are presently taking a prescription drug without consulting your physician or other health care professional. If you have kidney disease, take only under the supervision of a physician. May have a laxative effect. If pregnant or breast-feeding, ask a health professional before use.

Pregnancy or Breast Feeding

If pregnant or breast-feeding, ask a health professional before use.

Keep Out of Reach of Children

Package Label. Prinicpal Display Panel



Caution: Federal Law PROHIBITS the transfer of this drug to anyone other than the person whom prescribed and prohibits dispensing without a prescription, unless OTC. See outsert for add'l RX info KEEP OUT OF REACH OF CHILDREN store in cold, dry place at 68-77 F unless printed otherwise

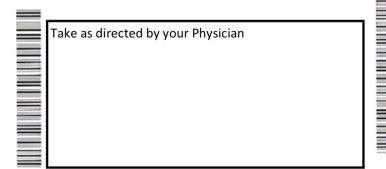
76519-1155-XX NDC: 76519-1155-XX

MAGNESIUM OXIDE 400mg TAB OTC #XX

Compare: Mag-Ox

MFG: RUGBY/MAJOR 00536-3521-41 LOT #: 51574

Account: 00-9999



MAGNESIUM OXIDE 400mg TAB OTC

EXP: 06/30/20 Lot #: 51574

MFG NDC: 00536-3521-41

MAGNESIUM OXIDE 400mg TAB OTC

NDC: 76519-1155-XX QTY: XX

EXP: 06/30/20 Lot #: 51574

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MAGNESIUM OXIDE 400mg TAB OTC

NDC: 76519-1155-XX QTY: XX

EXP: 06/30/20 Lot #: 51574

MFG NDC: 00536-3521-41

MAGNESIUM OXIDE 400mg TAB OTC

NDC: 76519-1155-XX QTY: XX

EXP: 06/30/20 Lot #: 51574

MFG NDC: 00536-3521-41

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Repack: H.J. Harkins., Inc. Grover Beach, CA 93433

MAGNESIUM OXIDE

magnesium oxide tablet

P	r	od	u	ct	Inf	01	ma	tion	
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:76519-1155

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthMAGNESIUM O XIDE (UNII: 3A3U0 GI71G) (MAGNESIUM CATION - UNII:T6 V3LHY838)MAGNESIUM O XIDE400 mg

Inactive Ingredients

3					
Ingredient Name	Strength				
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)					
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)					
STEARIC ACID (UNII: 4ELV7Z65AP)					
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)					

Product Characteristics					
Color	white	Score	score with uneven pieces		
Shape	ROUND	Size	11mm		
Flavor		Imprint Code	T		
Contains					

l	Packaging					
ı	# Item	Code	Package Description	Marketing Start Date	Marketing End Date	
ı	1 NDC:76	519-1155-6 60 in 1 CC	ONTAINER; Type 0: Not a Combination Product	06/16/2017		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part331	06/16/2017			

Labeler - H. J. Harkins Company Inc. (147681894)

Establishment					
Name	Address	ID/FEI	Business Operations		
H. J. Harkins Company Inc.		147681894	manufacture(76519-1155), relabel(76519-1155), repack(76519-1155)		

Revised: 12/2017 H. J. Harkins Company Inc.