

**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.*

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**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. Principal 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**

MAGNESIUM OXIDE 400mg TAB OTC #XX

Compare: Mag-Ox

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

Account: 00-9999

 Take as directed by your Physician 

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

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76519-1155
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MAGNESIUM OXIDE (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM OXIDE	400 mg

### Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

**Product Characteristics**

<b>Color</b>	white	<b>Score</b>	score with uneven pieces
<b>Shape</b>	ROUND	<b>Size</b>	11mm
<b>Flavor</b>		<b>Imprint Code</b>	T
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76519-1155-6	60 in 1 CONTAINER; 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.