

MAGNESIUM OXIDE- magnesium oxide tablet
Aphena Pharma Solutions - Tennessee, LLC

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.

Magnesium Oxide Tablets

ACTIVE INGREDIENT (In each tablet)

Magnesium Oxide 400mg (241.2mg elemental magnesium)

Purpose

Antacid

USES

Relieves: ■ acid indigestion ■ upset stomach

WARNINGS

Ask a doctor if you have:

kidney disease

Ask a doctor or pharmacist before use if you are:

taking a prescription drug. Antacids may interact with certain prescription drugs.

Do not take

more than 2 tablets in a 24 hour period or use the maximum dosage of this product for more than two weeks, except under the advise and supervision of a physician. May have a laxative effect.

If pregnant or breast-feeding,

ask a health professional before use.

Keep Out of Reach of Children.

DIRECTIONS

Antacid Directions: ■ take 1 tablet twice a day or as directed by a physician

Magnesium Supplement Directions: ■ take 1 to 2 tablets daily or as directed by a physician

OTHER INFORMATION

■ store at room temperature 59°-86° F (15°-30°C) ■ do not use if imprinted safety seal under cap is broken or missing

■ Magnesium content per tablet: 253 mg

INACTIVE INGREDIENTS

croscarmellose sodium, microcrystalline cellulose, magnesium stearate

Questions or Comments

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

call 804-270-4498, 8.30 am-4.30 pm ET, Monday - Friday

Repackaging Information

Please reference the **How Supplied** section listed above for a description of individual tablets. This drug product has been received by Aphenia Pharma - TN in a manufacturer or distributor packaged configuration and repackaged in full compliance with all applicable cGMP regulations. The package configurations available from Aphenia are listed below:

Count	400 mg
90	71610-172-60

Store between 20°-25°C (68°-77°F). See USP Controlled Room Temperature. Dispense in a tight light-resistant container as defined by USP. Keep this and all drugs out of the reach of children.

Repackaged by:



Cookeville, TN 38506

20181025JH

PRINCIPAL DISPLAY PANEL - 400 mg

NDC 71610-172 - Magnesium Oxide 400 mg



MAGNESIUM OXIDE

magnesium oxide tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:716 10 -172(NDC:54738-973)
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)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	white (Off)	Score	no score
Shape	ROUND	Size	12mm
Flavor		Imprint Code	AP;136
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:716 10 -172-60	90 in 1 BOTTLE; Type 0: Not a Combination Product	10/15/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	02/01/2016	

Labeler - Aphenia Pharma Solutions - Tennessee, LLC (128385585)

Establishment

Name	Address	ID/FEI	Business Operations
Aphenia Pharma Solutions - Tennessee, LLC		128385585	REPACK(71610-172)