

CALCIUM CARBONATE 10 GR (648 MG) (ANTACID)- calcium carbonate 10gr (648 mg) 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.

Drug Facts

Active ingredient (in each tablet)

Calcium Carbonate 10 gr (648 mg)

Purpose

Antacid

Uses

relieves

- acid indigestion
- heartburn
- sour stomach
- upset stomach associated with these symptoms

Warnings

Ask a doctor before use if you have

- kidney stones
- a calcium-restricted diet

Ask a doctor or pharmacist before use if you are

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

Stop use and ask a doctor if

symptoms last more than 2 weeks.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

Directions

- take one to four tablets daily
- do not take more than 4 tablets in 24 hours
- do not use the maximum dosage for more than two weeks

Other information

- each tablet contains: **calcium 260 mg**
- store at room temperature

Inactive ingredients

acacia, croscarmellose sodium, magnesium stearate, maltodextrin, microcrystalline cellulose, stearic acid

Questions or comments?

1-800-645-2158

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

This is a bulk package. Dispense contents with a child-resistant closure in a tight, light-resistant container as defined in the USP.

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	648 mg
180	71610-301-80

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

20190711JH

PRINCIPAL DISPLAY PANEL - 648 mg

NDC 71610-301 - Calcium Carbonate 648 mg Tablets



CALCIUM CARBONATE 10 GR (648 MG) (ANTACID)

calcium carbonate 10gr (648 mg) tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71610-301(NDC:0536-1206)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK) (CARBONATE ION - UNII:7UJQ5OPE7D, CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CARBONATE	648 mg

Inactive Ingredients

Ingredient Name	Strength
ACACIA (UNII: 5C5403N26O)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	PH046
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71610-301-60	90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/31/2019	
2	NDC:71610-301-65	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/16/2019	
3	NDC:71610-301-80	180 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/10/2019	
4	NDC:71610-301-92	270 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/31/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	02/28/2019	

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

Establishment

Name	Address	ID/FEI	Business Operations
Aphena Pharma Solutions - Tennessee, LLC		128385585	REPACK(71610-301)

Revised: 7/2019

Aphena Pharma Solutions - Tennessee, LLC