# MAGNACAL- calcium carbonate tablet, chewable Afassco 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 IN EACH TABLET- CALCIUM CARBONATE 420 MG

### **ANTACID**

Uses: For the relief of the following symptoms associated with:

- acid indigestion sour stomach
- heartburn upset stomach

Warnings:

Ask a doctor or health professional before use if you are:

- taking a prescription drug. Antacids may interact with certain prescription drugs.
- do not use a maximum dosage for more than 2 weeks except under the advice of a physician.

If pregnant or breast-feeding baby, 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 right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

#### Directions:

Adults and children: (12 years and older) 2 or more tablets chewed not to exceed18 tablets in a 24 hour period

Children: (under 12 years) Do not give to children under 12 years of age unless directed by a doctor.

### SEE ORIGINAL BOX FOR COMPLETE PRODUCT INFORMATION

Other Information:

Each tablet contains: 168 mg of elemental calcium.



2 Tablets

# Active Ingredients (In Each Tablet)

**Purpose** 

Calcium Carbonate 420 mg ......Antacid

# **Uses:** For the relief of the following symptoms associated with:

- acid indigestion
- sour stomach
- heartburn
- upset stomach

# Warnings:

# Ask a doctor or health professional before use if you are:

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

Questions? Contact Afassco Minden, NV 89423 Store at room temperature Tamper evident: Do not use packet if torn or cut.

# Warnings (continued)

· do not use a maximum dosage for more than 2 weeks except under the advice of a physician.

# Keep out of reach of children.

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

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### MAGNACAL

calcium carbonate tablet, chewable

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Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51532-0303
Route of Administration	ORAL		

### **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
CALCIUM CARBONATE (UNII: H0 G9379 FGK) (CARBONATE ION - UNII:7UJQ50 PE7D)	CALCIUM CARBONATE	420

Inactive	Ingredients

Ingredient Name	Strength	
STARCH, CORN (UNII: O8232NY3SJ)		
SUCROSE (UNII: C151H8M554)		
MAGNESIUM STEARATE (UNII: 70097M6130)		

MINT (UNII: FV98Z8GITP)	
ACACIA (UNII: 5C5403N26O)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	

Product Characteristics				
Color	white (WHITE)	Score	no score	
Shape	ROUND	Size	12mm	
Flavor	MINT	Imprint Code	FR8	
Contains				

ı	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:51532-0303-2	2 in 1 PACKET; Type 0: Not a Combination Product	10/25/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	04/07/2015	

# Labeler - Afassco Inc. (609982723)

# Registrant - ULTRAtab Laboratories, Inc. (151051757)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
ULTRA SEAL CORPORATION		085752004	pack(51532-0303)	

Establishment			
Name	Address	ID/FEI	Business Operations
ULTRATAB LABORATORIES, INC.		151051757	manufacture(51532-0303)

Revised: 9/2019 Afassco Inc.