# ANTACID- calcium carbonate tablet, chewable TYA Pharmaceuticals

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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# **Major Pharmaceuticals Antacid Tablets Drug Facts**

# **Active ingredient (in each tablet)**

Calcium carbonate USP 500mg

## **Purpose**

Antacid

#### Uses

## relieves

- heartburn
- sour stomach
- acid indigestion
- 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

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

## When using this product

- do not take more than 15 tablets in 24 hours
- do not use the maximum dosage for more than 2 weeks

# Keep out of reach of children.

#### **Directions**

• chew 2 - 4 tablets as symptoms occur, or as directed by a doctor

#### Other information

- each tablet contains: calcium 215 mg and magnesium 5 mg
- store at 20-25°C (68-77°F)

# **Inactive ingredients**

adipic acid, blue #1 aluminum lake, dextrose, flavors, maltodextrin, mineral oil, polyethylene glycol, powdered cellulose, red #40 aluminum lake, talc, yellow #5 aluminum lake (tartrazine), yellow #6

### Questions?

1-800-616-2471

# ANTACID (CALCIUM CARBONATE) TABLET, CHEWABLE

# ANTACID TABLETS(CALCIUM)

0904-1258-92

LOT:xxxx

EXP: XX-XX-XX

MFR: MAJOR

REPACKAGED BY: T.Y.A. PHARMACEUTICALS 2830 CRESCENT DR. TALLAHASSEE, FL 32301 (850) 385-0228

DOSE: SEE PACKAGE INSERT

#### **ANTACID**

calcium carbonate tablet, chewable

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:64725-1258(NDC:0904-1258)

Route of Administration ORAL

# **Active Ingredient/Active Moiety**

Ingredient Name
Basis of Strength
CALCIUM CARBONATE (UNII: H0 G9379 FGK) (CALCIUM CATION - UNII: 2M83C4R6 ZB)
CALCIUM CARBONATE
CALCIUM CARBONATE

Inactive Ingredients					
Ingredient Name	Strength				
ADIPIC ACID (UNII: 76 A0 JE0 FKJ)					
DEXTROSE (UNII: IY9 XDZ35W2)					
MALTO DEXTRIN (UNII: 7CVR7L4A2D)					
MINERAL O IL (UNII: T5L8T28FGP)					
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)					
PO WDERED CELLULO SE (UNII: SMD1X3XO9 M)					
TALC (UNII: 7SEV714R1U)					

Product Characteristics					
Color	RED, YELLOW, GREEN, ORANGE	Score	no score		
Shape	ROUND	Size	17mm		
Flavor	FRUIT (Cherry, lemon, lime, orange)	Imprint Code	L478		
Contains					

Packaging						
# Item Code	Package Description	Marketing Start Date	Marketing End Date			
1 NDC:64725-1258-1	150 in 1 BOTTLE					

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	part331	08/07/1992				

# Labeler - TYA Pharmaceuticals (938389038)

# Registrant - TYA Pharmaceuticals (938389038)

Establishment						
Name	Address	ID/FEI	Business Operations			
TYA Pharmaceuticals		938389038	RELABEL(64725-1258), REPACK(64725-1258)			

Revised: 11/2011 TYA Pharmaceuticals