

TC MAX- calcium carbonate powder, for solution

TC MAX- calcium carbonate

Romavision Investing 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 Ingredients (In each packet)

Calcium Carbonate (4000mg)

Purpose

Antacid

Indications

For the relief of:

- Heartburn
- Acid Indigestion
- Sour Stomach
- Upset stomach associated with these symptoms

Warnings

- Do not take more than 4 ounces in a 24 hour period
- Do not use the maximum dosage of this product for more than 2 weeks, except under the advice and supervision of a physician
- If pregnant or breast feeding check with your physician before using

Ask a doctor before use if you have

- kidney disease
- a magnesium restricted diet
- a calcium restricted diet

Keep this and all drugs out of the reach of children

Drug Interactions

Ask a doctor or pharmacist before use

- If you are presently taking a prescription drug. Antacids may interact with certain prescriptions drugs.

Directions for use

Add the entire contents of one packet to 8 ounces of cold water and mix well. Take 4 ounces once per day or as directed by a physician.

Other information

Each box contains Calcium 15%, Magnesium .85%, Sodium 2.4%

Inactive Ingredients:

Acacia Senegal Whole, Acesulfame-Potassium, Advantame, Artificial Flavor, Glycerin, Magnesium Hydroxide, Neotame, Sodium Bicarbonate, Sucrose, Sunflower Oil Mono and Diglycerides, Tapioca Starch, Thaumatin, Tocopherol Acetate, Tricalcium phosphate, Xanthan Gum

Principal Display Panel - 68 gram Packet Label

Vanilla Ice Cream Flavor

TC MAX

Buffered Suspension

68 grams

Corn Free Soy Free Protein Free Dairy Free Non GMO

Vanilla Ice Cream Flavor



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All ingredients are listed alphabetically as required by the FDA and come from CORN FREE, SOY FREE, DAIRY FREE, NON GMO sources.

For more information please visit www.tcmxcompany.com

Manufactured for Romavision LLC

3267 E 3300 S #119 Salt Lake City, UT, 84109

Customer Support: info@tcmxcompany.com

Principal Display Panel - 68 gram Packet Label

**Vanilla Ice Cream
Flavor**

TC MAX

Starter Kit

Buffered Suspension

Corn Free

Soy Free

Protein Free

Dairy Free

Non GMO

Vanilla Ice Cream
Flavor



Starter Kit Buffered Suspension

Corn Free Soy Free Protein Free Dairy Free Non GMO

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Contents

- 6 - TC Max 68 gram Packets
- Large Mixing Bottle
- Large Oral Syringe.
- Small Oral Syringe
- Funnel
- pH Testing Kit (pH chart and 5 - pH test strips)

All ingredients are listed alphabetically as required by the FDA and come from CORN FREE, SOY FREE, DAIRY FREE, NON GMO sources.

For more information please visit www.tmaxcompany.com
Manufactured for Romavision LLC
6709 W 119th St, Overland Park, KS, 66209
Customer Support: Info@tmaxcompany.com

TC MAX

calcium carbonate powder, for solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80733-005
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
calcium carbonate (UNII: H0G9379FGK) (calcium cation - UNII:2M83C4R6ZB)	calcium carbonate	4 g in 237 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C00X)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
STARCH, TAPIOCA (UNII: 24SC3U704I)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)	
SUNFLOWER OIL MONO/DIGLYCERIDES (UNII: HS7EB0C1ZH)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
XANTHAN GUM (UNII: TTV12P4NEE)	
NEOTAME (UNII: VJ597D52EX)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
THAUMATIN (UNII: KNC9Q0EE6G)	
SUCROSE (UNII: C151H8M554)	
ADVANTAME (UNII: 3ZA6810AWX)	
ACACIA SENEGAL WHOLE (UNII: QP4QYZ033C)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80733-005-01	237 mL in 1 PACKET; Type 0: Not a Combination Product	07/18/2019	
2	NDC:80733-005-05	5 in 1 BOX	07/18/2019	
2	NDC:80733-005-01	237 mL in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC monograph final	part331	06/03/2019	

TC MAX

calcium carbonate kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80733-007
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80733-007-06	1 in 1 BOX	07/18/2019	
1		1 in 1 KIT; Type 1: Convenience Kit of Co-Package		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	6 PACKET	1422 mL

Part 1 of 1

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STARCH, TAPIOCA (UNII: 24SC3U704I)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)	

SUNFLOWER OIL MONO/DIGLYCERIDES (UNII: HS7EB0C1ZH)
SUNFLOWER OIL (UNII: 3W1JG795YI)
XANTHAN GUM (UNII: TTV12P4NEE)
NEOTAME (UNII: VJ597D52EX)
SODIUM BICARBONATE (UNII: 8MDF5V39QO)
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SUCROSE (UNII: C151H8M554)
ADVANTAME (UNII: 3ZA6810AWX)
ACACIA SENEGAL WHOLE (UNII: QP4QYZ033C)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		6 in 1 NOT APPLICABLE		
1		237 mL in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	07/18/2019	

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OTC monograph final	part331	07/18/2019	

Labeler - Romavision Investing LLC (080808687)

Establishment

Name	Address	ID/FEI	Business Operations
Identipak, Inc.		942862350	MANUFACTURE(80733-005, 80733-007)