

TITRALAC PLUS- calcium carbonate, dimethicone tablet
iNova Pharmaceuticals Pty, Ltd

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 tablet)

Calcium carbonate 420 mg

(168 mg elemental calcium)

Simethicone 21 mg

Purpose

Antacid

Antigas

Uses

- relieves symptoms referred to as gas
- relieves:
 - heartburn
 - sour stomach
 - acid indigestion

Warnings

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 for more than 2 weeks.

Keep out of reach of children.

Directions

- chew, swallow or let melt in mouth two tablets every two or three hours as symptoms occur or as directed by a physician
- do not take more than 19 tablets in a 24 hour period or use maximum dosage for more than two weeks

Other information

- sugar free
- very low sodium content (1.5 mg/tablet)
- low aluminum content (1.0 mg/tablet)

Inactive ingredients

glycine, magnesium stearate, saccharin, spearmint oil, starch

- may also contain croscarmellose sodium

For your protection this bottle has a printed foil seal under the cap.

For Information: 1-800-537-2191

Made in Australia for 3M

3M Consumer Health Care

St. Paul, MN 55144-1000

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T7562

Principal Display Panel – Bottle Label**SPEARMINT FLAVOR****NDC 055298-013-10****FAST RELIEF****Titalac™****PLUS ANTACID****Simethicone Anti-Gas Formula****Calcium Rich • Sugar Free****Low Aluminum • Very Low Sodium****100 TABLETS 3M**

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Drug Facts (continued)

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FAST RELIEF

SPEARMINT FLAVOR

NDC 055298-013-10

Titalrac™

PLUS ANTACID

Simethicone Anti-Gas Formula

Calcium Rich • Sugar Free

Low Aluminum • Very Low Sodium

100 TABLETS 3M



0 51131 53937 2

TITRALAC PLUS			
calcium carbonate, dimethicone tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55298-013
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Calcium Carbonate (UNII: H0G9379FGK) (Calcium - UNII:SY7Q814VUP)	Calcium Carbonate	420 mg	
dimethicone (UNII: 92RU3N3Y1O) (dimethicone - UNII:92RU3N3Y1O)	dimethicone	21 mg	
Inactive Ingredients			
Ingredient Name	Strength		
glycine (UNII: TE7660XO1C)			
magnesium stearate (UNII: 70097M6I30)			

saccharin (UNII: FST467XS7D)	
spearmint oil (UNII: C3M81465G5)	
starch, corn (UNII: O8232NY3SJ)	

Product Characteristics

Color	white (White)	Score	no score
Shape	ROUND (Round)	Size	12mm
Flavor	SPEARMINT (SPEARMINT)	Imprint Code	TITRALAC;PLUS
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55298-013-10	100 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	01/01/2004	

Labeler - iNova Pharmaceuticals Pty, Ltd (750581035)

Establishment

Name	Address	ID/FEI	Business Operations
iNova Pharmaceuticals Pty, Ltd		750581035	MANUFACTURE

Revised: 5/2011

iNova Pharmaceuticals Pty, Ltd