

MI-ACID GAS RELIEF- simethicone tablet, chewable
Aidarex Pharmaceuticals 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.

Mi-Acid Gas Relief

Active ingredient (in each tablet)

Simethicone 80 mg

Purpose

Antigas

Enter section text here

Uses

relieves:

- pressure
- bloating
- symptoms referred to as gas

Warnings

Keep out of reach of children. In case of overdose, get medical help or contact a poison control center immediately.

Directions

- chew 2 to 4 tablets thoroughly as needed after meals and at bedtime.
- do not exceed 6 tablets per day unless directed by a physician.

Other information

- do not use if inner seal is broken.
- store at room temperature
- avoid high humidity and excessive heat, above 40⁰C (104⁰F)

Inactive ingredients

compressible sugar, dextrose, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, sorbitol

Questions

To Report Adverse Drug Event Call: (800) 616-2471

PDP

Mi-Acid Gas Relief

Relieves Gas Pain, Pressure and Bloating

Simethicone 80 mg/Antiflatulent

30 Chewable Tablets

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT, KEEP OUT OF REACH OF CHILDREN. STORE AT CONTROLLED ROOM TEMP 15-30C (59-86F)

Packaged and Distributed by: **AIDAREX PHARMACEUTICALS LLC.**

SIMETHICONE CHEW

80mg

30 TABS

EACH TABLET CONTAINS THE FOLLOWING ACTIVE INGREDIENTS:
SIMETHICONE.....80 MG
CHEWABLE

WHITE ROUND TABLET W/MANUFACTURE LOGO OC 103 ON ONE SIDE

GENERIC FOR : MYLANTA
NDC: 33261-0224-30

TAKE _____ EVERY _____ HOURS _____ TIMES A DAY
TOME _____ CADA _____ HORAS _____ VECES AL DIA

MFG: FOR: MAJOR PHARMACEUTICALS LIVONIA, MI 48150

RX QLS0000

SIMETHICONE CHEW. 80mg 30
NDC: 33261-0224-30
RXQLS0000

SIMETHICONE CHEW. 80mg 30
NDC: 33261-0224-30
RX QLS0000

SIMETHICONE CHEW. 80mg 30
NDC: 33261-0224-30
RX QLS0000

PEEL HERE
PATIENT LOG CHART
PEEL HERE

MI-ACID GAS RELIEF

simethicone tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:33261-224(NDC:0904-5068)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	80 mg

Inactive Ingredients

Ingredient Name	Strength
SUCROSE (UNII: C151H8M554)	
DEXTROSE (UNII: IY9XDZ35W2)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	WHITE	Score	no score
Shape	ROUND	Size	13mm

Flavor	PEPPERMINT	Imprint Code	GDC103	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:33261-224-30	30 in 1 BOTTLE, PLASTIC		
2	NDC:33261-224-60	60 in 1 BOTTLE, PLASTIC		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part332	03/02/2011		

Labeler - Aidarex Pharmaceuticals LLC (801503249)

Revised: 2/2014

Aidarex Pharmaceuticals LLC