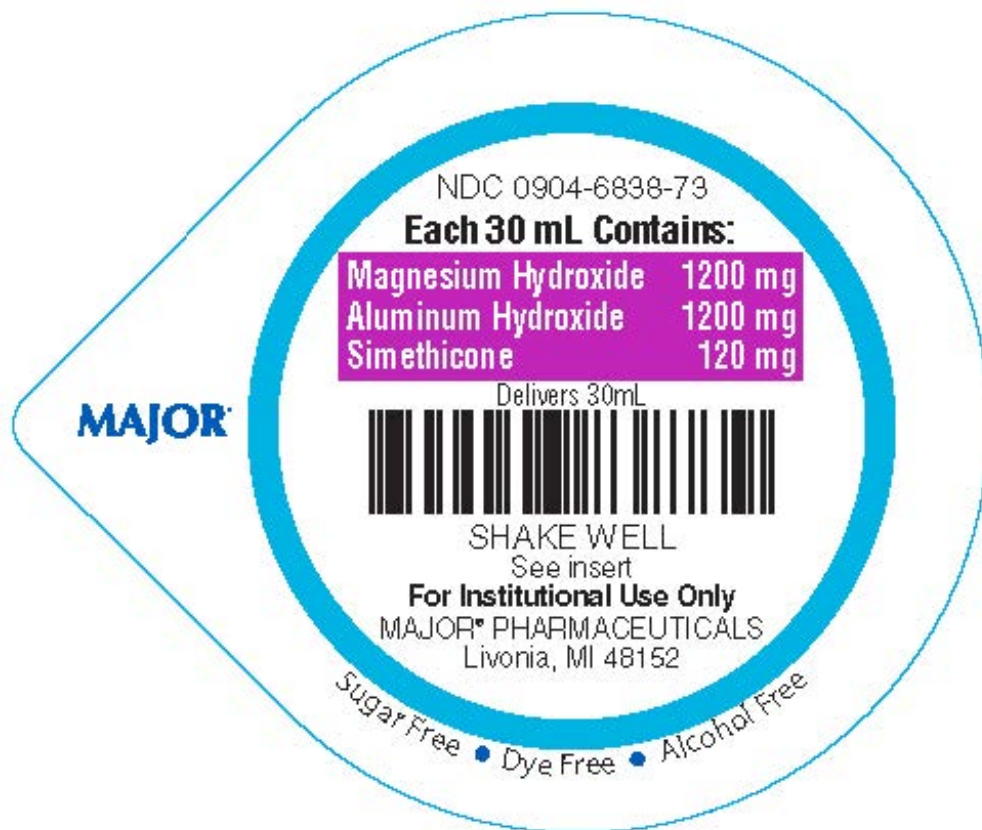


MAGNESIUM HYDROXIDE/ALUMINUM HYDROXIDE/SIMETHICONE- magnesium hydroxide, aluminum hydroxide, simethicone suspension
Major Pharmaceuticals

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.

Major Pharmaceuticals
Unit dose OTC Monograph drugs
MgOH-Al-OH-Simethicone

Magnesium hydroxide, Aluminum hydroxide, Simethicone 1200/1200/120 mg per 30 mL
Major Pharmaceutical OTC Monograph



NDC 0904-6838-73

Each 30 mL Contains:
Magnesium Hydroxide 1200 mg
Aluminum Hydroxide 1200 mg
Simethicone 120 mg
Delivers 30 mL
Shake Well
See Insert
For Institutional Use Only
MAJOR PHARMACEUTICALS
Livonia, MI 64152

Sugar Free - Dye Free - Alcohol Free

MgOH, AlOH, Simethicone 1200/1200/120 mg/30 mL

Directions

- do not exceed the maximum recommended daily dose in a 24 hour period
- shake well before use
- do not use the maximum daily dose for more than 2 weeks

Age (yr)	Dose (mL)
adults and children 12 years and over	30 mL, not more than 120 mL in 24 hours
children under 12 years	ask a doctor

MgOH, AlOH, Simethicone 1200/1200/120 mg/30 mL

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

MgOH, AlOH, Simethicone 1200/1200/120 mg/30 mL

Warnings

Ask a doctor before use if you have

- kidney disease
- a magnesium-restricted diet

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

- you have symptoms that last more than 2 weeks

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

MgOH, AlOH, Simethicone 1200/1200/120 mg/30 mL

Inactive ingredients citric acid, glycerin, microcrystalline cellulose, methyl cellulose, purified water, saccharin sodium, sodium citrate, spearmint oil, xanthan gum

MgOH, AlOH, Simethicone 1200/1200/120 mg/30 mL

Uses

- acid indigestion
- heartburn
- sour stomach
- upset stomach due to these symptoms
- pressure and bloating commonly referred to as gas

MgOH, AlOH, Simethicone 1200/1200/120 mg/30 mL

Active ingredient (in each 30 mL cup)

Magnesium hydroxide USP 1200 mg

Magnesium hydroxide USP 1200 mg

Simethicone 120 mg

MgOH, AlOH, Simethicone 1200/1200/120 mg/30 mL

Antacid

Antacid

Antigas

MgOH, AlOH, Simethicone 1200/1200/120 mg/30 mL

Other information

- each 30 mL contains: calcium 40 mg, sodium 25 mg, and magnesium 500 mg
- store at 20-25°C (68-77°F)
- protect from excessive moisture
- do not use if lid seal is open or damaged
- sugar free, dye free, alcohol free
- see bottom of cup for lot number and expiration date

MgOH, AlOH, Simethicone 1200/1200/120 mg/30 mL

Product Insert
Magnesium hydroxide/Aluminum hydroxide
/Simethicone
 NDC 0904-6838-73
 10 x 30 mL Unit Dose Cups

Drug Facts

<i>Active ingredients (in each 30 mL cup)</i>	<i>Purpose</i>
Aluminum hydroxide (equiv. to dried gel, USP) 1200 mg.....	Antacid
Magnesium hydroxide USP 1200 mg.....	Antacid
Simethicone 120 mg	Antigas

Uses ■ acid indigestion ■ heartburn ■ sour stomach
 ■ upset stomach due to these symptoms ■ pressure and bloating commonly referred to as gas

Warnings

Ask a doctor before use if you have

- kidney disease
- a magnesium-restricted diet

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 ■ you have symptoms that last more than 2 weeks

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

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

Directions

- do not exceed the maximum recommended daily dose in a 24 hour period
- shake well before use
- do not use the maximum daily dose for more than 2 weeks

Age (yr)	Dose (mL)
adults and children 12 years and over	30 mL, not more than 120 mL in 24 hours
children under 12 years	ask a doctor

Other information

- each 30 mL contains: calcium 40 mg, sodium 25 mg, and magnesium 500 mg
- store at 20-25°C (68-77°F) ■ protect from excessive moisture
- do not use if lid seal is open or damaged ■ sugar free, dye free, alcohol free
- see bottom of cup for lot number and expiration date

Inactive ingredients citric acid, glycerin, microcrystalline cellulose, methyl cellulose, purified water, sucralose, sodium citrate, spearmint oil, xanthan gum

Questions or comments?

Call 1-800-618-2471

MAJOR

MAJOR[®] PHARMACEUTICALS
 17177 N Laurel Park Dr., Suite 233
 Livonia, MI 48152

M-154
 C05035 R1
 Rev. 04/19

Re-order
 No. 701031



NDC 0904-6839-73

Each 30 mL Contains:

Magnesium Hydroxide 2400 mg

Aluminum Hydroxide 2400 mg

Simethicone 240 mg

Max

Delivers 30 mL

Shake Well

See Insert

For Institutional Use Only

MAJOR PHARMACEUTICALS

Livonia, MI 64152

Sugar Free - Dye Free - Alcohol Free

Magnesium hydroxide, Aluminum hydroxide, Simethicone 2400/2400/240 mg/30 mL

Directions

- do not exceed the maximum recommended daily dose in a 24 hour period
- shake well before use
- do not use the maximum daily dose for more than 2 weeks

Age (yr)	Dose (mL)
adults and children 12 years and over	30 mL, not more than 60 mL in 24 hrs.
children under 12	

Children under 12 years	ask a doctor
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Magnesium hydroxide, Aluminum hydroxide, Simethicone 2400/2400/240 mg/30 mL

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Magnesium hydroxide, Aluminum hydroxide, Simethicone 2400/2400/240 mg/30 mL

Warnings

Ask a doctor before use if you have

- kidney disease
- a magnesium-restricted diet

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

- you have symptoms that last for more than 2 weeks.

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

Magnesium hydroxide, Aluminum hydroxide, Simethicone 2400/2400/240 mg/30 mL

Inactive ingredients citric acid, glycerin, microcrystalline cellulose, methyl cellulose, purified water, saccharin sodium, sodium citrate, spearmint oil, xanthan gum

Magnesium hydroxide, Aluminum hydroxide, Simethicone 2400/2400/240 mg/30 mL

Uses

- acid indigestion
- heartburn
- sour stomach
- upset stomach due to these symptoms
- pressure and bloating commonly referred to as gas

Magnesium hydroxide, Aluminum hydroxide, Simethicone 2400/2400/240 mg/30 mL

Magnesium hydroxide, Aluminum hydroxide, Simethicone 2400/2400/240 mg/30 mL

Antacid

Antacid

Antigas

Magnesium hydroxide, Aluminum hydroxide, Simethicone 2400/2400/240 mg/30 mL

Other information

- each 30 mL contains: calcium 40 mg, sodium 25 mg, and magnesium 1000 mg
- store at 20-25°C (68-77°F) -

- protect from excessive moisture
- do not use if lid seal is open or damaged -
- sugar free, dye free, alcohol free
- see bottom of cup for lot number and expiration date

Magnesium hydroxide, Aluminum hydroxide, Simethicone 2400/2400/240 mg/30 mL

Product Insert
Magnesium hydroxide/Aluminum hydroxide
/Simethicone Max
 NDC 0904-6839-73
 10 x 30 mL Unit Dose Cups

Drug Facts

<i>Active ingredients (in each 30 mL cup)</i>	<i>Purpose</i>
Aluminum hydroxide (equiv. to dried gel, USP) 2400 mg.....	Antacid
Magnesium hydroxide USP 2400 mg.....	Antacid
Simethicone 240 mg	Antigas

Uses ■ acid indigestion ■ heartburn ■ sour stomach
 ■ upset stomach due to these symptoms ■ pressure and bloating commonly referred to as gas

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- shake well before use
- do not use the maximum daily dose for more than 2 weeks

Age (yr)	Dose (mL)
adults and children 12 years and over	30 mL, not more than 60 mL in 24 hours
children under 12 years	ask a doctor

Other information

- each 30 mL contains: calcium 40 mg, sodium 25 mg, and magnesium 1000 mg
- store at 20-25°C (68-77°F) ■ protect from excessive moisture
- do not use if lid seal is open or damaged ■ sugar free, dye free, alcohol free
- see bottom of cup for lot number and expiration date

Inactive ingredients citric acid, glycerin, microcrystalline cellulose, methyl cellulose, purified water, sucralose, sodium citrate, spearmint oil, xanthan gum

Questions or comments?

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MAJOR

MAJOR[®] PHARMACEUTICALS
 17177 N Laurel Park Dr., Suite 233
 Livonia, MI 48152

M-154
 C05036 R1
 Rev. 04/19

Re-order
 No. 701032

MAGNESIUM HYDROXIDE/ALUMINUM HYDROXICE/SIMETHICONE

magnesium hydroxide,aluminum hydroxice,simethicone suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-6839
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	240 mg in 30 mL
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDROXIDE - UNII:5QB0T2IUN0)	ALUMINUM HYDROXIDE	2400 mg in 30 mL
MAGNESIUM HYDRO XIDE (UNII: NBZ3QY004S) (HYDROXIDE ION - UNII:9159UV381P, MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM HYDROXIDE	2400 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
METHYLCELLULOSE (15 CPS) (UNII: NPU9M2E6L8)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	

Product Characteristics

Color	white (Suspension)	Score	
Shape		Size	
Flavor	SPEARMINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-6839-73	10 in 1 CASE	12/27/2019	
1		10 in 1 TRAY		
1		30 mL in 1 CUP, UNIT-DOSE; 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	12/27/2019	

MAGNESIUM HYDROXIDE/ALUMINUM HYDROXICE/SIMETHICONE

magnesium hydroxide/aluminum hydroxice/simethicone suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-6838
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	120 mg in 30 mL
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDRO XIDE - UNII:5QB0T2IUN0)	ALUMINUM HYDROXIDE	1200 mg in 30 mL
MAGNESIUM HYDRO XIDE (UNII: NBZ3QY004S) (HYDROXIDE ION - UNII:9159UV381P, MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM HYDROXIDE	1200 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
METHYLCELLULOSE (15 CPS) (UNII: NPU9M2E6L8)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	white (Suspension)	Score	
Shape		Size	
Flavor	SPEARMINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-6838-73	10 in 1 CASE	12/27/2019	
1		10 in 1 TRAY		
1		30 mL in 1 CUP, UNIT-DOSE; 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	12/27/2019	

Labeler - Major Pharmaceuticals (191427277)

Registrant - Plastikon Healthcare, LLC (041717941)

Establishment

Name	Address	ID/FEI	Business Operations
Plastikon Healthcare, LLC		041717941	manufacture(0904-6838, 0904-6839)

Revised: 11/2019

Major Pharmaceuticals