# MINTOX- aluminum hydroxide, magnesium hydroxide, simethicone suspension ATLANTIC BIOLOGICALS CORP.

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 Mintox<sup>™</sup> Drug Facts

#### Active ingredients (in each 10 mL)

Aluminum hydroxide (equiv. to dried gel, USP) 400 mg Magnesium hydroxide 400 mg Simethicone 40 mg

#### Purpose

Antacid

Antigas

#### Uses

for the relief of

- acid indigestion
- heartburn
- sour stomach
- upset stomach associated with 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

presently taking a prescription drug. Antacids may interact with certain prescription drugs.

#### When using this product

do not take more than 80 mL in a 24-hour period, or use the maximum dosage for more than 2 weeks, except under the advice and supervision of a physician

#### Keep out of reach of children.

#### **Directions**

shake well before using

- only use the dose cup provided
- adults and children 12 years and older: take 10 mL to 20 mL four times a day or as directed by a
  physician
- do not take more than 80 mL in 24 hours or use the maximum dosage for more than 2 weeks
- children under 12 years: consult a physician

#### Other information

- each 10 mL contains: magnesium 175 mg
- does not meet USP requirements for preservative effectiveness
- store at 20-25°C (68-77°F)
- protect from freezing

#### **Inactive ingredients**

butylparaben, flavor, hypromellose, microcrystalline cellulose and carboxymethylcellulose sodium, peppermint oil, propylparaben, purified water, saccharin sodium, simethicone emulsion, sorbitol, sorbitol solution

#### Questions or comments?

1-800-616-2471

#### **Principal Display Panel**

Regluar Strength

 $Mintox^{TM}$ 

Antacid/Antigas

Aluminum Hydroxide ■ Magnesium Hydroxide ■ Simethicone

Fast Relief of:

Heartburn

Acid Indigestion

Pressure and Bloating

Mint Flavor

Compare to the active ingredients of Maalox® Advanced

NDC 17856-6764-01

ALUMINUM HYDROXIDE/MAGNESIUM HYDROXIDE/SIMETHICONE ORAL SUSPENSION

1200MG/1200MG/120MG/30ML See package insert for indications and dosage schedule

Store at 20-25°C (68-77°F) Protect from freezing. \*\*SHAKE WELL\*\*

ANTACID/ANTIGAS MINT FLAVOR

Keep this and all Medication out of the reach of children

17856-6764-01 MINTOX

Dosage: 30 ML

Qty: 50 Cups

GTIN: 1785667641 S/N: 000000000000001

Exp: 11/21/19 Lot: 000000 OTC

17856676401

Packaged by: Unit Dose Solutions

Morrisville, NC 27560

Distributed by: AtlanticBiologicals

Corp, Miami FI 33179

Call to Reorder: 800.509.7592

#### **MINTOX**

aluminum hydroxide, magnesium hydroxide, simethicone suspension

#### **Product Information**

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:17856-6764(NDC:0904-6764)Route of AdministrationORAL

#### **Active Ingredient/Active Moiety**

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Ingredient Name	Basis of Strength	Strength		
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDRO XIDE - UNII:5QB0T2IUN0)	ALUMINUM HYDRO XIDE	400 mg in 10 mL		
MAGNESIUM HYDRO XIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6 V3LHY838, HYDRO XIDE ION - UNII:9159 UV381P)	MAGNESIUM HYDRO XIDE	400 mg in 10 mL		
DIMETHICO NE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	40 mg in 10 mL		

Inactive Ingredients				
Ingredient Name	Strength			
BUTYLPARABEN (UNII: 3QPI1U3FV8)				
HYPROMELLOSES (UNII: 3NXW29 V3WO)				
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)				
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)				
PEPPERMINT OIL (UNII: AV092KU4JH)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
WATER (UNII: 059QF0KO0R)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
SORBITOL (UNII: 506T60A25R)				
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)				

Product Characteristics			
Color	WHITE (opaque)	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:17856-6764- 1	50 in 1 BOX, UNIT-DOSE	01/13/2021	
	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	part332	05/21/2019	

## Labeler - ATLANTIC BIOLOGICALS CORP. (047437707)

Establishment			
Name	Address	ID/FEI	Business Operations
ATLANTIC BIOLOGICALS CORP.		047437707	repack(17856-6764), relabel(17856-6764)

Revised: 1/2021 ATLANTIC BIOLOGICALS CORP.