

MINTOX - aluminum hydroxide, magnesium hydroxide, dimethicone 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.

Active ingredients (in each 5 mL teaspoonful)

Aluminum hydroxide 200 mg (equivalent to dried gel, USP)

Magnesium hydroxide 200 mg

Simethicone 20mg

Purposes

Antacid

Antigas

Uses

relieves

- heartburn
- sour stomach
- acid indigestion
- the symptoms referred to as gas

Warnings

Ask a doctor before use if you have

- kidney disease
- a magnesium-restricted diet

taking a prescription drug. **Ask a doctor or pharmacist before use if you are**

Antacids may interact with certain prescription drugs.

symptoms last more than 2 weeks **Stop use and ask a doctor if**

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

Keep out of reach of children.

Directions

- shake well before use
- adults and children 12 years and older: take 2 to 4 teaspoonfuls four times a day, or as directed by a doctor
- do not take more than 16 teaspoonfuls in 24 hours or use the maximum dosage for more than 2 weeks
- children under 12 years: ask a doctor

Other information

- magnesium 85 mg, sodium 1 mg **each 5 mL teaspoonful contains:**
- store at room temperature
- protect from freezing
- keep tightly closed
- **TAMPER-EVIDENT: Do not use if breakaway band on bottle is missing or broken.**

Inactive ingredients

benzyl alcohol, butylparaben, carboxymethylcellulose sodium, flavor, hypromellose, microcrystalline cellulose, propylparaben, purified water, saccharin sodium, sorbitol solution

MINTOX (ALUMINUM HYDROXIDE, MAGNESIUM HYDROXIDE, DIMETHICONE) SUSPENSION

17856-5721-03

**ALUMINUM
HYDROXIDE/MAGNESIUM
HYDROXIDE/SIMETHICONE
(MINTOX) ORAL SUSPENSION**

See package insert for indications and dosage schedule

Store at room temperature and avoid freezing.
****SHAKE WELL****
 KEEP OUT OF THE REACH OF CHILDREN.



Rev. 01/19

17856-5721-03

MINTOX

Dosage: **1200 MG/1200
MG/120 MG/30
ML**

Qty: **50 Cups**



GTIN: 1785657213
 S/N: 34929300000029
 Exp: 04/11/20
 Lot: 349293

OTC



17856572103

Packaged by: Unit Dose Solutions
 Morrisville, NC 27560

Distributed by: AtlanticBiological
 Corp, Miami FL 33179

Call to Reorder: 800.509.7592

aluminum hydroxide, magnesium hydroxide, dimethicone suspension

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17856-5721(NDC:0904-5721)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDRO XIDE - UNII:5QB0T2IUN0)	ALUMINUM HYDRO XIDE	200 mg in 5 mL
MAGNESIUM HYDRO XIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838, HYDRO XIDE ION - UNII:9159UV381P)	MAGNESIUM HYDRO XIDE	200 mg in 5 mL
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	20 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BUTYL PARABEN (UNII: 3QP1IU3FV8)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17856-5721-3	30 mL in 1 CUP; Type 0: Not a Combination Product	01/26/2021	
2	NDC:17856-5721-5	5 mL in 1 CUP; Type 0: Not a Combination Product	01/26/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	02/01/2011	

Labeler - ATLANTIC BIOLOGICALS CORP. (047437707)

Registrant - ATLANTIC BIOLOGICALS CORP. (047437707)

Establishment

Name	Address	ID/FEI	Business Operations
ATLANTIC BIOLOGICALS CORP.		047437707	RELABEL(17856-5721) , REPACK(17856-5721)

Revised: 1/2021

ATLANTIC BIOLOGICALS CORP.