MINTOX MAXIMUM STRENGTH- aluminum hydroxide, magnesium hydroxide, dimethicone suspension
NuCare Pharmaceuticals,Inc.

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 400 mg (equivalent to dried gel, USP)

Magnesium hydroxide 400 mg

Simethicone 40mg

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

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 more than 2 weeks

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

Keep out of reach of children.

Directions

• shake well before use

• do not take more than 8 teaspoonfuls in 24 hours or use the maximum dosage for more than 2 weeks

• adults and children 12 years and older: take 2 to 4 teaspoonfuls two times a day, or as directed by a doctor

• children under 12 years: ask a doctor

Other information

• **each 5 mL teaspoonful contains:** magnesium 165 mg, sodium 1 mg

• store at room temperature

• protect from freezing

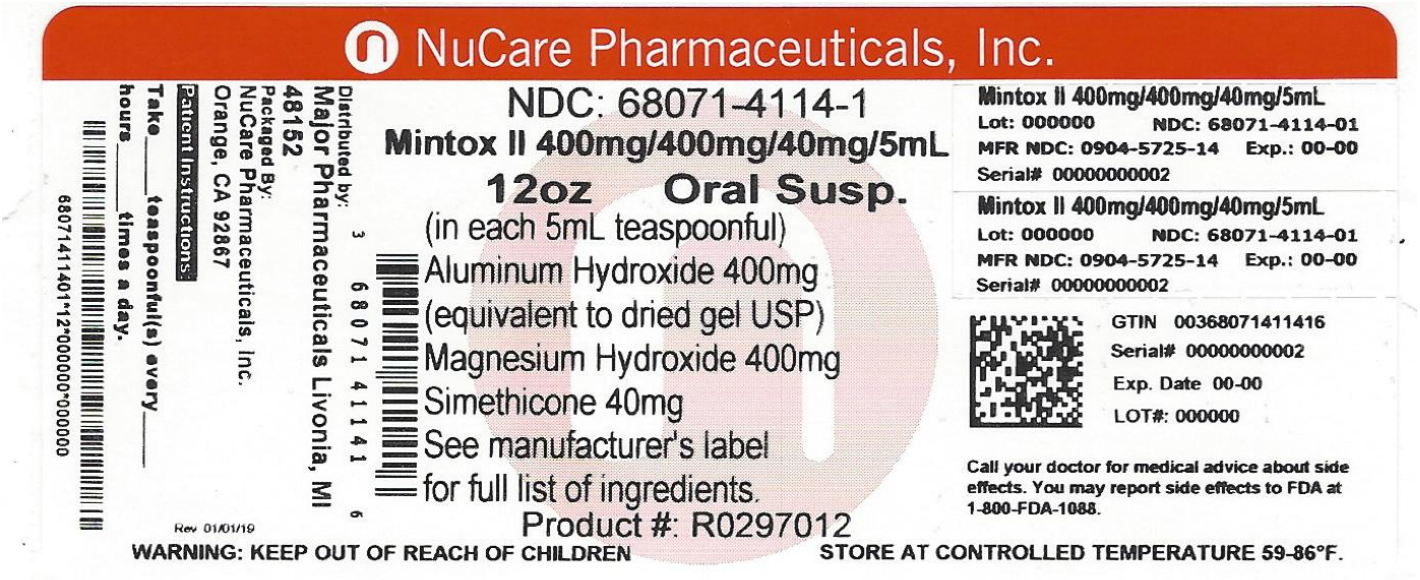
• keep tightly closed

• **TAMPER-EVIDENT: Do not use if breakaway band on bottle cap is missing or broken.**

Inactive ingredients

benzyl alcohol, butylparaben, caramel color, carboxymethylcellulose sodium, D and C yellow no.10, flavor, glycerin, hypromellose, microcrystalline cellulose, propylparaben, purified water, saccharin sodium, sorbitol solution

package Label



MINTOX MAXIMUM STRENGTH
aluminum hydroxide, magnesium hydroxide, dimethicone suspension

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68071-4114(NDC:0904-5725)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) (ALUMINUM HYDROXIDE - UNII:5QB0T2IUN0)	ALUMINUM HYDROXIDE	400 mg in 5 mL
MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S) (MAGNESIUM CATION - UNII:T6V3LHY838, HYDROXIDE ION - UNII:9159UV381P)	MAGNESIUM HYDROXIDE	400 mg in 5 mL
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	40 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BUTYLPARABEN (UNII: 3QPI1U3FV8)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	LEMON (lemon)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-4114-1	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/09/2017	

Marketing Information

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

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals,Inc.		010632300	relabel(68071-4114)

Revised: 2/2021 NuCare Pharmaceuticals,Inc.