

OHTAS ISAN ANTACID - calcium carbonate, sodium bicarbonate powder
OHTA'S ISAN CO., LTD

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.

Drug Facts

Active Ingredients (in each spoonful)

Precipitated calcium carbonate 497 mg
Sodium bicarbonate 600 mg

Purpose

Precipitated calcium carbonate Antacid
Sodium bicarbonate Antacid

Uses

relieves: ■ heartburn ■ sour stomach ■ acid indigestion ■ upset stomach due to these symptoms

Warnings

Do not use more than 3 spoonfuls in a 24-hour period, or use the maximum dosage of this product for more than 2 weeks, except under the advice and supervision of a physician.

Ask a doctor or pharmacist before use if you are

- presently taking a prescription drug. Antacids may interact with certain prescription drugs.
- on a sodium-restricted diet.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

Direction

take 1 spoonful (using the spoon included with this can) with water, 3 times daily.

Other Information

each spoonful contains: sodium 164 mg.

Inactive ingredients

cinnamon bark, citrus unshiu peel, clove, fennel, gentian, *l*-menthol, nutmeg, powdered picrasma wood, magnesium carbonate.

Principal Display Panel - Can Label

Ohta's Isan NDC 49631-178-21

ANTACID POWDER

NET WT 2.65 OZ (75g)

Principal Display Panel - Can Label

Ohta's Isan NDC 49631-178-22

ANTACID POWDER

NET WT 4.94 OZ (140g)

OHTAS ISAN ANTACID

calcium carbonate, sodium bicarbonate powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49631-178
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Calcium Carbonate (UNII: H0G9379FGK) (Carbonate Ion - UNII:7UJQ5OPE7D)	Calcium Carbonate	1 g in 1 g
Sodium Bicarbonate (UNII: 8MDF5V39QO) (Bicarbonate Ion - UNII:HN1ZRA3Q20)	Sodium Bicarbonate	1 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
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Cinnamon (UNII: 5S29HWU6QB)	
Tangerine (UNII: KH3E3096OO)	
Clove (UNII: K48IKT5321)	
Fennel (UNII: 557II4LLC3)	
Gentiana Lutea Root (UNII: S72O3284MS)	
Levomethol (UNII: BZ1R15MTK7)	
Nutmeg (UNII: AEE24M3MQ9)	
Picrasma Quassioides Wood (UNII: 75EIV4LX7W)	
Magnesium Carbonate (UNII: 0E53J927NA)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49631-178-21	75 g in 1 CAN; Type 0: Not a Combination Product		
2	NDC:49631-178-22	140 g in 1 CAN; 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	10/16/2000	

Labeler - OHTA'S ISAN CO., LTD (690771738)

Revised: 3/2016

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