

**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 packet <1.3g>)

Precipitated calcium carbonate 497 mg

Sodium bicarbonate 600 mg

Purpose

Antacid

Antacid

Uses

relieves:

- heartburn
- sour stomach
- acid indigestion
- upset stomach due to these symptoms

Warnings

Do not take more than 3 packets 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 of a 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 packet with water, 3 times daily, or as directed by a physician.

Other information

each packet contains: sodium 164 mg.

Inactive ingredients

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

Principal Display Panel - 16 Packets Box Label

NDC 49631-178-13

Graphic - Ohta's Isan Logo

Ohta's Isan ANTACID POWDER

Heartburn Herb Flavored

Acid Upset

Indigestion Stomach

OHTA'S ISAN MADE IN JAPAN 16 Packets



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:HN1Z RA3Q20)	SODIUM BICARBONATE	1 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
CINNAMON (UNII: 5S29HWU6QB)	
TANGERINE (UNII: KH3E3096OO)	
CLOVE (UNII: K48IKT5321)	
FENNEL (UNII: 557II4LLC3)	
GENTIANA LUTEA ROOT (UNII: S72O3284MS)	
LEVOMENTHOL (UNII: BZ1R15MTK7)	
NUTMEG (UNII: AEE24M3MQ9)	
PICRAMNA QUASSIOIDES WOOD (UNII: 75EIV4LX7W)	
MAGNESIUM CARBONATE (UNII: 0E53J927NA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49631-178-13	1 in 1 BOX	07/01/2017	
1		16 in 1 DOSE PACK		
1		1.3 g in 1 PACKET; 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	07/01/2017	

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

Name	Address	ID/FEI	Business Operations
OHTA'S ISAN CO.,LTD.		715739137	manufacture(49631-178)

