

**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.*

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**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)

The label features a dark blue header with the brand name 'Ohta's Isan' in white, followed by 'ANTACID POWDER' and the Japanese name '太田胃散' in red. Below this is a small illustration of two green leaves. The net weight 'NET WT 2.65 OZ (75g)' is printed at the bottom left. The right side of the label contains a safety warning: 'DO NOT USE IF IMPRINTED SAFETY SEAL AROUND THIS CAN IS BROKEN OR MISSING.' Below this are three columns of text: 'Drug Facts' (listing active ingredients: Precipitated calcium carbonate 497 mg and Sodium bicarbonate 600 mg), 'Warnings' (advising to ask a doctor before use if taking prescription drugs, on a sodium-restricted diet, or pregnant/breast-feeding), and 'Direction' (take 1 spoonful 3 times daily). A 'Drug Facts (continued)' box on the right lists inactive ingredients and manufacturer information: OHTA'S ISAN CO., LTD., 3-2, SENGOKU 2-CHOME, BUNKYO-KU, TOKYO 112-0011, JAPAN. A barcode with the number 4118217821 is on the far right.

## Principal Display Panel - Can Label

Ohta's Isan NDC 49631-178-22

ANTACID POWDER

NET WT 4.94 OZ (140g)

The label features a dark blue header with the brand name 'Ohta's Isan' in white, followed by 'ANTACID POWDER' and the Japanese name '太田胃散' in red. Below this is a small illustration of two green leaves. The net weight 'NET WT 4.94 OZ (140g)' is printed at the bottom left. The right side of the label contains a safety warning: 'DO NOT USE IF IMPRINTED SAFETY SEAL AROUND THIS CAN IS BROKEN OR MISSING.' Below this are three columns of text: 'Drug Facts' (listing active ingredients: Precipitated calcium carbonate 497 mg and Sodium bicarbonate 600 mg), 'Warnings' (advising to ask a doctor before use if taking prescription drugs, on a sodium-restricted diet, or pregnant/breast-feeding), and 'Direction' (take 1 spoonful 3 times daily). A 'Drug Facts (continued)' box on the right lists inactive ingredients and manufacturer information: OHTA'S ISAN CO., LTD., 3-2, SENGOKU 2-CHOME, BUNKYO-KU, TOKYO 112-0011, JAPAN. A barcode with the number 4118217822 is on the far left.

## OHTAS ISAN ANTACID

calcium carbonate, sodium bicarbonate powder

**Product Information**

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

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>CALCIUM CARBONATE</b> (UNII: H0G9379FGK) (CARBONATE ION - UNII:7UJQ50PE7D)	CALCIUM CARBONATE	1 g in 1 g
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO) (BICARBONATE ION - UNII:HN1Z RA3Q20)	SODIUM BICARBONATE	1 g in 1 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>CINNAMON</b> (UNII: 5S29HWU6QB)	
<b>TANGERINE</b> (UNII: KH3E30960O)	
<b>CLOVE</b> (UNII: K48IKT5321)	
<b>FENNEL</b> (UNII: 557II4LLC3)	
<b>GENTIANA LUTEA ROOT</b> (UNII: S72O3284MS)	
<b>LEVOMENTHOL</b> (UNII: BZ1R15MTK7)	
<b>NUTMEG</b> (UNII: AEE24M3MQ9)	
<b>PICRAMNA QUASSIOIDES WOOD</b> (UNII: 75EIV4LX7W)	
<b>MAGNESIUM CARBONATE</b> (UNII: 0E53J927NA)	

**Packaging**

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

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part331	10/16/2000	

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

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
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OHTA'S ISAN CO.,LTD.		715739137	manufacture(49631-178)
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Revised: 11/2022

OHTA'S ISAN CO.,LTD.