

**OHTAS ISAN ANTACID - magnesium aluminosilicate, calcium carbonate, sodium bicarbonate tablet**

**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 tablet)***

|                                |          |
|--------------------------------|----------|
| Magnesium aluminometasilicate  | 83.3 mg  |
| Precipitated calcium carbonate | 133.3 mg |
| Sodium bicarbonate             | 133.3 mg |

***Purpose***

|                                      |         |
|--------------------------------------|---------|
| Magnesium aluminometasilicate .....  | Antacid |
| Precipitated calcium carbonate ..... | Antacid |
| Sodium bicarbonate .....             | Antacid |

***Uses***

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

***Warnings***

**Do not use** more than 9 tablets 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 doctor.

**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***

swallow 3 tablets with a glass of water after meals, 3 times daily

***Other Information***

- **each tablet contains:** sodium 36.7 mg. ■ keep the carton. It contains important information.
- store at 20°-25°C (68°-77°F) ■ protect from moisture

**Inactive ingredients**

cinnamon bark, cinnamon oil, citrus unshiu peel, clove, fennel, fennel oil, gentian, lemon oil, menthol, magnesium stearate, microcrystalline cellulose, nutmeg, powdered picrasma wood.

**PRINCIPAL DISPLAY PANEL**

NDC 49631-212-01

**Ohta's Isan ANTACID TABLETS**

Heartburn Acid Indigestion Upset Stomach

45 TABLETS

**Manufactured by**

**OHTA'S ISAN CO., LTD.**

3-2, SENGOKU 2-CHOME, BUNKYO-KU,  
TOKYO 112-0011, JAPAN

PRODUCT OF JAPAN

DO NOT USE IF A CARTON IS DAMAGED OR FOIL SEAL IS BROKEN.

Lot. No.

Exp. Date



## OHTAS ISAN ANTACID

magnesium aluminosilicate, calcium carbonate, sodium bicarbonate tablet

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:49 631-212

Route of Administration ORAL

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength  | Strength |
|---|--------------------|----------|
| Almasilate (UNII: OZQ8O62H53) (Almasilate - UNII:OZQ8O62H53)              | Almasilate         | 83.3 mg  |
| Calcium Carbonate (UNII: H0G9379FGK) (Carbonate Ion - UNII:7UJQ5OPE7D)    | Calcium Carbonate  | 133.3 mg |
| Sodium Bicarbonate (UNII: 8MDF5V39QO) (Bicarbonate Ion - UNII:HN1ZRA3Q20) | Sodium Bicarbonate | 133.3 mg |

### Inactive Ingredients

| Ingredient Name                                | Strength |
|--|----------|
| Cinnamon (UNII: 5S29HWU6QB)                    |          |
| Cinnamon Oil (UNII: E5GY4I6YCZ)                |          |
| Tangerine (UNII: KH3E3096OO)                   |          |
| Clove (UNII: K48IKT5321)                       |          |
| Clove Oil (UNII: 578389D6D0)                   |          |
| Fennel (UNII: 557II4LLC3)                      |          |
| Fennel Oil (UNII: 59AAO5F6HT)                  |          |
| Gentiana Lutea Root (UNII: S72O3284MS)         |          |
| Lemon Oil (UNII: I9GRO824LL)                   |          |
| Menthol (UNII: L7T10EIP3A)                     |          |
| Magnesium Stearate (UNII: 70097M6I30)          |          |
| Cellulose, Microcrystalline (UNII: OP1R32D61U) |          |
| Nutmeg (UNII: AEE24M3MQ9)                      |          |
| Picrasma Quassioides Wood (UNII: 75EIV4LX7W)   |          |

### Product Characteristics

|          |                      |              |          |
|----------|----------------------|--------------|----------|
| Color    | YELLOW (Pale Yellow) | Score        | no score |
| Shape    | ROUND                | Size         | 10mm     |
| Flavor   |                      | Imprint Code |          |
| Contains |                      |              |          |

### Packaging

| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:49631-212-01 | 1 in 1 CARTON       |                      |                    |
| 1 |                  | 45 in 1 PACKAGE     |                      |                    |

### Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part331                                  | 12/01/2012           |                    |

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

