

ZANTANOL TAB.- magnesium oxide, magnesium aluminum hydrate tablet
Cho-A Pharm.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.

Zantanol Tab.

Active Ingredients

Magnesium Aluminum Hydrate 100mg

Magnesium Oxide 50mg

Purpose

Antacid

Keep out of reach of children

• In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Uses

Helps relieve symptoms associated with indigestion: pain in the upper abdomen, heartburn, indigestion, nausea.

Warnings

For oral use only

Use only the recommended dosage

Do not use if you have

- hemodyscrasia
- kidney, liver, bowel, stomach, and duodenum disease
- immunological disorder (asthma,rheumatism)
- previously experienced sensitivity to this medication
- dialysis

Do not use if the user under 15 and over 80 years old.

When using this product

- do not take other stomach medicine.
- do not take alcohol

Ask a doctor, dentist, or pharmacist before use if the user

- take other medication
- take medical treatment
- have allergic reaction for drug
- are over 65 years old
- have sore throat, cough, or fever
- are having continuously stomachaches
- have kidney disease

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

Store at cool temperature and dry place with a closed container. Avoid direct sunlight. - Store in a container other than its original container is equivalent to misuse. In order to prevent the reduction of drug efficacy, keep the product in its original container for storage.

Directions

- do not take more than the recommended dose
- adults (over 15 and under 80 years old): take 2 tablets per session. After 5 hours if symptoms last 0.5-1g per session, 1-3 times per day, before meal. Do not take over 4 tablets a day.

Inactive Ingredients

Ranitidine Hydrochloride, Magnesium Aluminosilicate, Low Substituted Hydroxypropylcellulose, Crospovidone, Hydroxypropylcellulose, Magnesium Stearate, Opadry white 80W68912, Purified Water

Zantanol Tab.



ZANTANOL TAB.

magnesium oxide, magnesium aluminum hydrate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58354-101
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MAGNESIUM OXIDE (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM OXIDE	50 mg in 424 mg
MAGALDRATE (UNII: 6V88E24N5T) (MAGALDRATE ANHYDROUS - UNII:0MFM55849I)	MAGALDRATE	50 mg in 424 mg

Inactive Ingredients

Ingredient Name	Strength
ALMASILATE (UNII: OZQ8O62H53)	
RANITIDINE HYDROCHLORIDE (UNII: BK76465IHM)	
LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE (8% HYDROXYPROPYL: 140000 MW) (UNII: U466TXA0AK)	
CROSPVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
water (UNII: 059QF0KO0R)	

Product Characteristics

Color	white	Score	no score
Shape	capsule	Size	13mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58354-101-02	10 in 1 PACKAGE	02/28/2017	
1	NDC:58354-101-01	424 mg in 1 CAPSULE; 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	02/28/2017	

Labeler - Cho-A Pharm.Co.,Ltd. (688056831)

Registrant - Cho-A Pharm.Co.,Ltd. (688056831)

Establishment

Name	Address	ID/FEI	Business Operations
Cho-A Pharm.Co.,Ltd.		688056831	manufacture(58354-101)

