

HIS ULC MINT BLUE- calcium carbonate tablet, chewable
SAMSUNG PHARM IND. 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.

ACTIVE INGREDIENT

Active ingredient: Calcium carbonate 350mg

INACTIVE INGREDIENT

Inactive ingredients:

Magnesium hydroxide, L-menthol, Aspartame, Sugar, Povidone, Lactose Hydrate, Spirulina color, Mint flavor, Calcium carboxymethylcellulose, Magnesium stearate

PURPOSE

Effective for: Relieves:Heartburn, Sour stomach, Acid indigestion, Upset stomach associated with these symptoms

WARNINGS

1. The following people must consult a doctor, dentist or pharmacist before administering the drug.
 - (1) Patients with kidney disorders
 - (2) Patients taking other drugs
2. Patients must immediately stop administration of the drug and consult a doctor, dentist or pharmacist if the following symptoms are observed. Carry these instructions when visiting.
 - (1) If symptoms of constipation or diarrhea occur while administering this drug
 - (2) When no improvement is detected after 2 weeks of administration
3. Other precautions when administering this drug
 - (1) Follow the given instructions and dosages
 - (2) When administering to children, it must be administered under the supervision of a parent or guardian
4. Storage directions
 - (1) Store in places out of the reach of children
 - (2) Keep away from direct sunlight and store sealed in cool places with low humidity.
 - (3) Do not store in different containers in order to prevent misuse and preserve quality (Only store in container if it has been specifically labelled and is not open to misuse)

KEEP OUT OF REACH OF CHILDREN

KEEP OUT OF REACH OF CHILDREN

INDICATIONS AND USAGE

adult :take 2 tablets, 4/3 tablets for kids 11 to 14, 1 tablet for kids 8 to 10, 2/3 tablet for kids 5 to 7, 1/2 tablet for kids to 3 to 4, 3 times a day. Taken between meals or at bedtime
Taking a melt in your mouth and chew.

DOSAGE AND ADMINISTRATION

adult :take 2 tablets, 4/3 tablets for kids 11 to 14, 1 tablet for kids 8 to 10, 2/3 tablet for kids 5 to 7, 1/2 tablet for kids to 3 to 4, 3 times a day. Taken between meals or at bedtime
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PACKAGE LABEL. PRINCIPAL DISPLAY PANEL

Exp. date
Lot no.

New Concept ANTACID!

HIS-ULC Mint Blue Tab.

New Concept ANTACID!

HIS-ULC Mint Blue tab

+ Fresh Breath

Relieve : Heartburn
Sour stomach
Acid indigestion

10T

New Concept ANTACID!

HIS-ULC Mint Blue Tab.

Made in Korea



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DRUG FACTS	Tamper Evident Packet- Sealed for your protection. Do not use if packet is damaged or open
Active ingredient (per tablet) calcium carbonate 350mg	
Inactive ingredient Magnesium hydroxide, L-menthol, Aspartame, Sugar, Povidone, Lactose Hydrate, Spirulina color, Mint flavor, Calcium carboxymethylcellulose, Magnesium stearate	
Description White round chewable pill with a blue semi-circle	
Effective for Relieves : Heartburn, Sour stomach, Acid indigestion, Upset stomach associated with these symptoms	
Dosage adult : take 2 tablets, 4/3 tablets for kids 11 to 14, 1 tablet for kids 8 to 10, 2/3 tablet for kids 5 to 7, 1/2 tablet for kids to 3 to 4, 3 times a day. Taken between meals or at bedtime. Taking a melt in your mouth and chew.	
Directions for Administration	
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HIS ULC MINT BLUE

calcium carbonate tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49789-060
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Calcium carbonate (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	Calcium carbonate	350 mg in 492 mg

Inactive Ingredients

Ingredient Name	Strength
magnesium hydroxide (UNII: NBZ3QY004S)	
Aspartame (UNII: Z0H242BBR1)	

Product Characteristics

Color	white	Score	2 pieces
Shape	ROUND	Size	10mm
Flavor	MINT	Imprint Code	SSPN
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49789-060-01	492 mg in 1 BLISTER PACK		

Marketing Information

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

Labeler - SAMSUNG PHARM IND. CO., LTD. (687744425)**Registrant** - SAMSUNG PHARM IND. CO., LTD. (687744425)**Establishment**

Name	Address	ID/FEI	Business Operations
SAMSUNG PHARM IND. CO., LTD.		687744425	manufacture(49789-060)