

LEGEND PREMIUM HEARTBURN CHEWABLE- calcium carbonate tablet
ADVANCED PHARMACEUTICAL SERVICES, INC. DBA AFFORDABLE QUALITY
PHARMACEUTICALS

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.

LEGEND PREMIUM HEARTBURN GAS RELIEF CHEWABLE

Active Ingredients

Calcium carbonate 750 mg.

Simethicone 80 mg.

Purpose

- Antacid
- Antigas

Warnings

Do not use if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor or pharmacist before use if you are presently taking a prescription drug. Antacids may interact with certain prescription drugs.

When using this product

- Do not take more than 5 chewable tablets in a 24-hour period
- Do not use the maximum dosage of this product for more than 2 weeks except under the advice and supervision of a physician
- Constipation may occur

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

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Keep out of reach of children.

Uses for the relief of

- acid indigestion
- heartburn
- sour stomach
- upset stomach associated with these symptoms
- bloating, pressure, or stuffed feeling commonly referred to as gas

Directions

- adults and children 12 years and over: fully chew then swallow 1 or 2 chewable tablets as symptoms occur, or as directed by a doctor.
- children under 12 years: consult a doctor
- do not take more than 5 chewable tablets in a 24-hour period.

Other information

- each chewable tablet contains: calcium 300 mg
- store at room temperature. Avoid excessive heat above 40oC (104 F).

Inactive Ingredients

Dextrose monohydrate, Saccharin sodium, Sucrose, Dokudami extract, FD&C Red No. 3, Povidone K30, Water, Xylitol, Sorbitol, Magnesium Stearate, Peppermint, Silicon Dioxide

Product Label



LEGEND PREMIUM HEARTBURN CHEWABLE

calcium carbonate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13411-844
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	750 mg
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	80 mg

Inactive Ingredients

Ingredient Name	Strength
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCROSE (UNII: C151H8M554)	
HOULTUYNIA CORDATA FLOWERING TOP (UNII: RH041UUZ22)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
POVIDONE K30 (UNII: U725QWY32X)	
WATER (UNII: 059QF0KO0R)	
XYLITOL (UNII: VCQ006KQ1E)	
SORBITOL (UNII: 506T60A25R)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
PEPPERMINT (UNII: V95R5KMY2B)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	pink	Score	no score
Shape	ROUND	Size	2mm
Flavor	PEPPERMINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13411-844-24	24 in 1 BOX; Type 0: Not a Combination Product	06/22/2020	
2	NDC:13411-844-30	30 in 1 BOX; Type 0: Not a Combination Product	06/22/2020	
3	NDC:13411-844-60	60 in 1 BOX; Type 0: Not a Combination Product	06/22/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part331	06/22/2020	

Labeler - ADVANCED PHARMACEUTICAL SERVICES, INC. DBA AFFORDABLE QUALITY PHARMACEUTICALS
(187498279)

Revised: 6/2020

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