LEGEND PREMIUM HEARTBURN CHEWABLE RELIEF- 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 RELIEF CHEWABLE

Active Ingredient

Calcium carbonate 500 mg.

Purpose

- Antacid

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.

Keep out of reach of children.

Uses for the relief of

● acid indigestion

● heartburn

● sour stomach

● upset stomach associated with these symptoms

Directions

● adults and children 12 years and over: fully chew then swallow 2 to 3 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 200 mg
● store at room temperature. Avoid excessive heat above 40°C (104°F).

Inactive Ingredients

Dextrose monohydrate, Saccharin sodium, Sucrose, Dokudami extract, FD&C Blue No. 1, FD&C yellow No. 5, Povidone K30, Water, Xylitol, Sorbitol, Magnesium Stearate, Peppermint, Silicon Dioxide

Product Label

Marquette of blister

LEGEND PREMIUM HEARTBURN CHEWABLE RELIEF

calcium carbonate tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:13411-845
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	500 mg

Inactive Ingredients	
Ingredient Name	**Strength**
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	

SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCROSE (UNII: C151H8M554)	
HOUTTUYNIA CORDATA FLOWERING TOP (UNII: RH041UUZ22)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
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	green	**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:13411-845-24	24 in 1 BOX; Type 0: Not a Combination Product	06/22/2020	
2	NDC:13411-845-30	30 in 1 BOX; Type 0: Not a Combination Product	06/22/2020	
3	NDC:13411-845-60	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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