GALEO- dihydroxydibutylether liquid
Cho-A Pharm.Co.,Ltd.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Galeo

Active Ingredients

Dihydroxydibutylether 5g

Purpose

Digestive aid

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: such as bloating, nausea, digestive discomfort, eructation.

Warnings

For oral use only

Do not use if you have
• glaucoma
• difficulty in urination, prostate disease (risk of ischuria)
• billiary atresia
• cholelithiasis
• liver disease
• previously experienced sensitivity to this medication

Ask a doctor, dentist, or pharmacist before use if the user takes
• other medication
• reserpine derivatives
• cholagogue

Stop use and ask a doctor if
• there is no remission of symptoms after several dosages for 2 weeks.

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.

This product contains Sodium Benzoate: it may cause minor irritation on skin, eye, and mucous membrane.

Directions

• do not take more than the recommended dose
• adults: take 0.5-1g per session, 1-3 times per day, before meal.

Inactive Ingredients

Sodium Benzoate, D-Sorbitol Solution 70%, Anhydrous Citric Acid, Purified Water

Galeo

GALEO
dihydroxydibutylether liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58354-100
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
4,4'-OXYDI-2-BUTANOL (UNII: CR6X2Y7NRR) (4,4'-OXYDI-2-BUTANOL - UNII:CR6X2Y7NRR)	4,4'-OXYDI-2-BUTANOL	5 g in 50 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SORBITOL (UNII: 506T60A25R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:58354-100-02	1 in 1 PACKAGE	02/28/2017	
1	NDC:58354-100-01	50 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		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(58354-100)

Revised: 2/2017 Cho-A Pharm.Co.,Ltd.