HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use LEGUBETI™ safely and effectively. See full prescribing information for LEGUBETI™.

LEGUBETI (acetylcysteine) for oral solution
Initial U.S. Approval: 1963

----------INDICATIONS AND USAGE----------

LEGUBETI is indicated as an antidote to prevent or lessen hepatic injury, which may occur following the ingestion of a potentially hepatotoxic quantity of acetaminophen, in adults and pediatric patients.
It is essential to initiate treatment as soon as possible after the overdose and, in any case, within 24 hours of acetaminophen ingestion. (1)

----------DOSAGE AND ADMINISTRATION----------

Pre-Treatment Assessment Following Acute Ingestion (2.1):
Obtain a plasma or serum sample to assay for acetaminophen concentration at least 4 hours after acetaminophen ingestion.

- If the time of acetaminophen ingestion is unknown:
  - Administer a loading dose of LEGUBETI immediately.
  - Obtain an acetaminophen concentration to determine the need for continued treatment.
- If the acetaminophen concentration cannot be obtained (or is unavailable or uninterpretable) within the 8-hour time interval after acetaminophen ingestion or there is clinical evidence of acetaminophen toxicity:
  - Administer a loading dose of LEGUBETI immediately and continue treatment for a total of 17 doses.
- If the patient presents more than 8 hours after ingestion and the time of acute acetaminophen ingestion is known:
  - Administer a loading dose of LEGUBETI immediately.
  - Obtain an acetaminophen concentration to determine the need for continued treatment.
- If the patient presents less than 8 hours after ingestion and the time of acute acetaminophen ingestion is known and the acetaminophen concentration is known:
  - Use the Rumack-Matthew nomogram (Figure 1) to determine whether or not to initiate treatment with LEGUBETI. (2.2)

Nomogram for Estimating Potential for Hepatotoxicity from Acute Acetaminophen Ingestion (2.2):

- See the Full Prescribing Information for instructions on how to use the nomogram to determine the need for loading and maintenance dosing.

Recommended Adult and Pediatric Dosage (2.3):

- LEGUBETI is for oral administration only; not for nebulization or intratracheal instillation.
- Loading dose: 140 mg/kg
- Maintenance doses: 70 mg/kg repeated every 4 hours for a total of 17 doses.
- See Full Prescribing Information for weight-based dosage and preparation and administration instructions.

----------DOSAGE FORMS AND STRENGTHS----------

For oral solution: 500 mg and 2.5 grams of acetylcysteine (3)

----------CONTRAINDICATIONS----------

None (4)

----------WARNINGS AND PRECAUTIONS----------

- Hypersensitivity Reactions, including urticaria, angioedema, bronchospasm, pruritus, flushing, other rash, chest tightness, and hypotension. Discontinue LEGUBETI unless deemed essential to patient management and the reactions can be otherwise controlled. (5.1)
- Risk of Upper Gastrointestinal Hemorrhage: Consider the risk/benefit for patients at risk of hemorrhage (e.g., those with esophageal varices, peptic ulcers, etc.) versus the risk of developing hepatic toxicity, and treat with LEGUBETI accordingly. (5.2)

----------ADVERSE REACTIONS----------

Most common adverse reactions are nausea and vomiting, other gastrointestinal symptoms, and rash with or without fever. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Galephar Pharmaceutical Research Inc. at 1-800-984-7536 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling

Revised: 02/2024

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

LEGUBETI, is indicated to prevent or lessen hepatic injury, which may occur following the ingestion of a potentially hepatotoxic quantity of acetaminophen, in adults and pediatric patients. It is essential to initiate treatment as soon as possible after the overdose and, in any case, within 24 hours of acetaminophen ingestion.

2 DOSAGE AND ADMINISTRATION

2.1 Pretreatment Assessment and Testing Following Acute Acetaminophen Ingestion

The following recommendations are related to acute acetaminophen ingestion.

1. Assess the history and timing of acetaminophen ingestion as an overdose.
    - The reported history of the quantity of acetaminophen ingested as an overdose is often inaccurate and is not a reliable guide to therapy.

2. Obtain the following laboratory tests to monitor hepatic and renal function and electrolyte and fluid balance: aspartate aminotransferase (AST), alanine aminotransferase (ALT), bilirubin, international normalized ratio (INR), creatinine, blood urea nitrogen (BUN), blood glucose, and electrolytes.

3. Obtain a plasma or serum sample to assay for acetaminophen concentration at least 4 hours after ingestion. Acetaminophen concentrations obtained earlier than 4 hours post-ingestion may be misleading as they may not represent maximum acetaminophen concentrations.

4. If the time of acute acetaminophen ingestion is unknown:
    - Administer a loading dose of LEGUBETI immediately *[see Dosage and Administration (2.3)]*.
    - Obtain an acetaminophen concentration to determine need for continued treatment *[see Dosage and Administration (2.2)]*

5. If the acetaminophen concentration cannot be obtained (or is unavailable or uninterpretable) within the 8-hour time interval after acetaminophen ingestion or there is clinical evidence of acetaminophen toxicity:
    - Administer a loading dose of LEGUBETI immediately and continue treatment for a total of 17 doses *[see Dosage and Administration (2.3)]*.

6. If the patient presents more than 8 hours after ingestion and the time of acute acetaminophen ingestion is known:
    - Administer a loading dose of LEGUBETI immediately *[see Dosage and Administration (2.3)]*.
    - Obtain acetaminophen concentration to determine need for continued treatment *[see Dosage and Administration (2.2)]*.

7. If the patient presents less than 8 hours after ingestion and the time of acute acetaminophen ingestion is known and the acetaminophen concentration is known:
    - Use the Rumack-Matthew nomogram (*Figure 1*) to determine whether or not to initiate treatment with LEGUBETI *[see Dosage and Administration (2.2)]*.

2.2 Nomogram for Estimating Potential for Hepatotoxicity from Acute Acetaminophen Ingestion and Need for LEGUBETI Treatment

If the timing of the acute acetaminophen ingestion is known and the results of the acetaminophen concentration are available within 8 hours of acetaminophen ingestion:

- Refer to the Rumack-Matthew nomogram (*see Figure 1*) to determine whether or not to initiate treatment with LEGUBETI.
- Initiation of LEGUBETI depends on the acetaminophen concentration and also the clinical presentation of the patient.

The nomogram may underestimate the hepatotoxicity risk in patients with chronic alcoholism, malnutrition, or CYP2E1 enzyme inducing drugs (e.g., isoniazid), and consideration should be given to treating these patients even if the acetaminophen concentrations are in the nontoxic range.

Loading Dose

For patients whose acetaminophen concentrations are at or above the "possible" toxicity line (dotted line in nomogram):

- Administer a loading dose of LEGUBETI *[see Dosage and Administration (2.3)]*.

For patients with an acute overdose due to an extended-release acetaminophen if the acetaminophen concentration at 4 hours post ingestion is below the possible toxicity line then obtain a second sample for acetaminophen concentration 8 to 10 hours after the acute ingestion. If the second value is at or above the "possible" toxicity line (dotted line in nomogram):

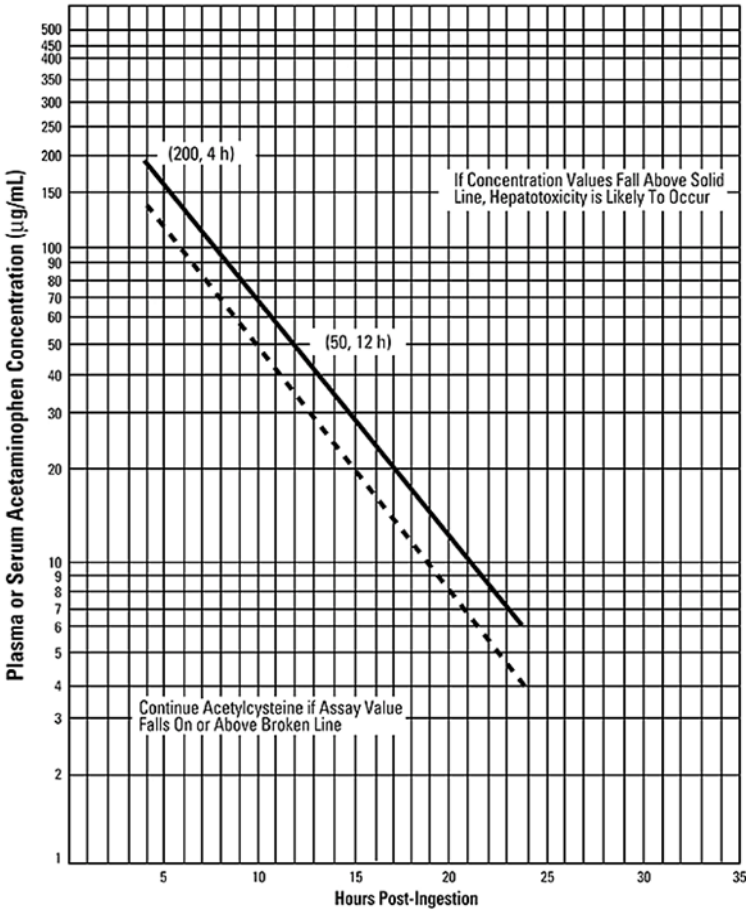
- Administer a loading dose of LEGUBETI *[see Dosage and Administration (2.3)]*.

For patients whose values are below the "possible" toxicity line, but time of ingestion was unknown, or sample was obtained less than 4 hours after ingestion:

- Administer a loading dose of LEGUBETI *[see Dosage and Administration (2.3)]*.

For patients whose values are below the "possible" toxicity line and time of ingestion is known and the sample was obtained more than 4 hours after ingestion, do not administer LEGUBETI because there is minimal risk of hepatotoxicity.

Figure 1 Rumack-Matthew Nomogram for Estimating Potential for Hepatotoxicity from Acetaminophen Poisoning – Plasma or Serum Acetaminophen Concentration versus Time (hours) Post-acetaminophen Ingestion (Adapted from Rumack and Matthew, Pediatrics 1975; 55:871−876.)



Maintenance Dose

Determine need for continued treatment with LEGUBETI after the loading dose. Choose ONE of the following based on the acetaminophen concentration:

The acetaminophen concentration is above the possible toxicity line according to the nomogram (see *Figure 1*):

- Continue LEGUBETI treatment with the maintenance dose for 17 doses *[see Dosage and Administration (2.3)]*.
- Monitor hepatic and renal function and electrolytes throughout treatment.

The acetaminophen concentration could not be obtained:

- Continue LEGUBETI treatment with the maintenance dose for 17 doses *[see Dosage and Administration (2.3)]*.
- Monitor hepatic and renal function and electrolytes throughout treatment.

For patients whose acetaminophen concentration is below the "possible" toxicity line (*see Figure 1*) and time of ingestion is known and the sample was obtained more than 4 hours after ingestion:

- Discontinue LEGUBETI.

The acetaminophen concentration was in the non-toxic range, but time of ingestion was unknown or less than 4 hours:

- Obtain a second sample for acetaminophen concentration and consider the patient's clinical status to decide whether or not to continue LEGUBETI treatment.
- If there is any uncertainty as to patient's risk of developing hepatotoxicity, it is recommended to administer a complete treatment course under medical observation with appropriate monitoring.

Continued Therapy After Completion of Loading and Maintenance Doses

In cases of suspected massive overdose, or with concomitant ingestion of other substances, or in patients with preexisting liver disease; the absorption and/or the half-life of acetaminophen may be prolonged. In such cases, consideration should be given to the need for continued treatment with LEGUBETI beyond a total of 17 maintenance doses.

Acetaminophen levels and ALT/AST and INR should be checked after the last maintenance dose. If acetaminophen levels are still detectable, or if the ALT/AST are still increasing or the INR remains elevated; the maintenance doses should be continued and the treating physician should contact a US regional poison center at 1-800-222-1222, or alternatively, a "special health professional assistance line for acetaminophen overdose" at 1-800-525-6115 for assistance with dosing recommendations.

2.3 Recommended Dosage and Preparation and Administration Instructions in Adults and Pediatrics for Acute Acetaminophen Ingestion

- LEGUBETI is for oral administration only; not for nebulization or intratracheal instillation.

- Adults and Pediatrics: The recommended loading dose of LEGUBETI is 140 mg/kg. Administer a first maintenance dose of 70 mg/kg 4 hours after the loading dose. Repeat 70 mg/kg maintenance dose every 4 hours for a total of 17 maintenance doses.

Preparation and Administration Instructions

- Dissolve the appropriate number of 2.5 gram and/or 500 mg LEGUBETI packets in the volume of caffeine-free diet cola or other diet soft drink, as indicated in dosing tables and text below, based upon patient weight.

- Once the powder is dissolved, administer the oral solution immediately.

- Solutions should be freshly prepared for each dose and utilized within 1 hour.

- If the patient vomits an oral dose of LEGUBETI within 1 hour of administration, repeat that dose.

- If the patient is persistently unable to retain the orally administered acetylcysteine, LEGUBETI may be administered by nasoduodenal tube. An intravenous formulation of acetylcysteine may also be considered.

Patients Weighing 20 kg and Greater

[Tables 1 and 2] provide the weight-based loading and maintenance doses, respectively, of LEGUBETI for patients weighing 20 kg and greater. For patients weighing 20 to 59 kg dissolve LEGUBETI powder in 150 mL of caffeine-free diet cola or other diet soft drink. For patients weighing 60 kg and greater dissolve LEGUBETI powder in 300 mL of caffeine-free diet cola or other diet soft drink.

Table 1: LEGUBETI Loading Dose

For patients weighing **60 kg or greater.** Dissolve LEGUBETI powder in **300 mL** of caffeine-free diet cola or other diet soft drinks			
Body weight (Kg)	Actual Acetylcysteine Dose to be Administered	Number of LEGUBETI packets to dissolve in caffeine-free diet cola or other diet soft drinks	
		2.5 grams packets	500 mg packets
100 or greater*	15 grams	6	0
90 to 99	14 grams	5	3
80 to 89	13 grams	5	1
70 to 79	11 grams	4	2
60 to 69	10 grams	4	0
For patients weighing **20 kg to 59 kg.** Dissolve LEGUBETI powder in **150 mL** of caffeine-free diet cola or other diet soft drinks			
50 to 59	8 grams	3	1
40 to 49	7 grams	2	4
30 to 39	6 grams	2	2
20 to 29	4 grams	1	3

*No specific studies have been conducted to evaluate the necessity of dose adjustments in patients weighing over 100 kg. Limited information is available regarding the dosing requirements of patients that weigh more than 100 kg.

Table 2: LEGUBETI Maintenance Dose

For patients weighing **60 kg or greater.** Dissolve LEGUBETI powder in **300 mL** of caffeine-free diet cola or other diet soft drinks			
Body weight (Kg)	Actual Acetylcysteine Dose to be administered	Number of LEGUBETI packets to dissolve in caffeine-free diet cola or other diet soft drinks	
		2.5 grams packets	500 mg packets
100 or greater*	7.5 grams	3	0
90 to 99	7 grams	2	4
80 to 89	6.5 grams	2	3
70 to 79	5.5 grams	2	1
60 to 69	5 grams	2	0
For patients weighing **20 kg to 59 kg.** Dissolve LEGUBETI powder in **150 mL** of caffeine-free diet cola or other diet soft drinks			
50 to 59	4 grams	1	3
40 to 49	3.5 grams	1	2
30 to 39	3 grams	1	1
20 to 29	2 grams	0	4

*No specific studies have been conducted to evaluate the necessity of dose adjustments in patients weighing over 100 kg. Limited information is available regarding the dosing requirements of patients that weigh more than 100 kg.

Patients Weighing 1 to 19 kg
Dissolve 5 grams (equivalent to two 2.5-gram LEGUBETI powder packets) in 100 mL of water to create a 50 mg/mL solution. Calculate the loading and maintenance doses using the patient's kilogram weight:

Loading dose: Calculate the dose by multiplying the patient's kilogram weight by 140 mg/kg and dividing by the concentration of the solution (50 mg/mL). The result is the dose in mL for administration using an oral syringe.

Maintenance dose: Calculate the dose by multiplying the patient's kilogram weight by 70 mg/kg and dividing by the concentration of the solution (50 mg/mL). The result is the dose in mL for administration using an oral syringe.

3 DOSAGE FORMS AND STRENGTHS

For Oral Solution:

- 500 mg of acetylcysteine: white powder in a packet printed with "Lot Number and Expiration Date" on one side
- 2.5 grams of acetylcysteine: white powder in a packet printed with "Lot Number and Expiration Date" on one side

4 CONTRAINDICATIONS

None

5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity Reactions

Generalized urticaria, angioedema, bronchospasm, pruritus, flushing, other rash, chest tightness, and hypotension have been observed in patients receiving oral acetylcysteine for acetaminophen overdose. If this occurs or other allergic symptoms appear, treatment with LEGUBETI should be discontinued unless it is deemed essential, and the allergic symptoms can be otherwise controlled.

5.2 Risk of Upper Gastrointestinal Hemorrhage

Occasionally severe and persistent vomiting occurs as a symptom of acute acetaminophen overdose. Treatment with oral LEGUBETI may aggravate the vomiting. Patients at risk of gastric hemorrhage (e.g., esophageal varices, peptic ulcers, etc.) should be evaluated concerning the risk of upper gastrointestinal hemorrhage versus the risk of developing hepatic toxicity, and treatment with LEGUBETI given accordingly.

Dilution of LEGUBETI [*see Dosage and Administration (2.3)*] minimizes the propensity of oral acetylcysteine to aggravate vomiting.

6 ADVERSE REACTIONS

The following adverse reactions are described, or described in greater detail, in other sections of the labeling:

- Hypersensitivity Reactions [*see Warnings and Precautions (5.1)*]
- Risk for Upper Gastrointestinal Hemorrhage [*see Warnings and Precautions (5.2)*]

The most common adverse reactions have been identified from clinical studies or post marketing reports of acetylcysteine. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. The most common adverse reactions were nausea, vomiting, other gastrointestinal symptoms, and rash with or without fever.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Available data from published case reports and case series over decades of use with acetylcysteine during pregnancy have not identified an increased risk of major birth defects, miscarriage or other adverse maternal or fetal outcomes. Treatment of acetaminophen overdose should not be delayed because potentially toxic acetaminophen plasma levels may increase the risk of maternal or fetal morbidity and mortality *(see Clinical Considerations)*. In animal reproduction studies, no teratogenic effects were observed with oral administration of acetylcysteine to pregnant rats and rabbits during organogenesis at doses up to 0.6 times the maximum recommended human dose (based on body surface area) of about 560 mg/kg (total dose on first day of treatment) [*see Data*]. Acetylcysteine lysine, the active ingredient in LEGUBETI, was not tested in animal reproduction studies.

The background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Clinical Considerations

Disease-Associated Maternal and/or Embryo/Fetal Risk

Although acetaminophen and acetylcysteine cross the placenta, there have been no adverse maternal or fetal outcomes associated with acetylcysteine use during pregnancy. Treatment in pregnant women with acetaminophen overdose should not be delayed because potentially toxic acetaminophen plasma levels may increase the risk of maternal and fetal morbidity and mortality.

Data

Animal Data

No teratogenic effects were observed in embryo-fetal development studies of acetylcysteine in rats at oral doses up to 2,000 mg/kg/day (0.6 times the maximum recommended human dose based on body surface area) or in rabbits at oral doses up to 1,000 mg/kg/day (0.6 times the maximum recommended human dose based on body surface area) administered during organogenesis.

8.2 Lactation

Risk Summary

There is no information regarding the presence of acetylcysteine in human milk, or the effects of acetylcysteine on the breastfed infant or on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for LEGUBETI and any potential adverse effects on the breastfed infant from LEGUBETI or from the underlying maternal condition.

8.4 Pediatric Use

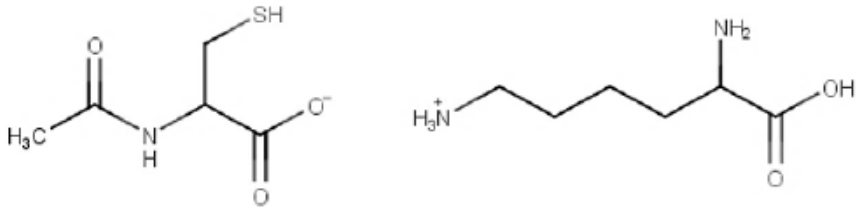
LEGUBETI is indicated in pediatric patients as an antidote to prevent or lessen hepatic injury which may occur following the ingestion of a potentially hepatotoxic quantity of acetaminophen. There is no recommended dosage for pediatric patients weighing less than 1 kg. [*see Dosage and Administration (2.3)*].

8.5 Geriatric Use

Clinical studies of acetylcysteine did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience with acetylcysteine has not identified differences in the responses between elderly and younger patients.

11 DESCRIPTION

LEGUBETI (acetylcysteine) for oral solution is an antidote for acetaminophen overdose. The drug substance is acetylcysteine lysine and is a white to almost white powder, freely soluble in water, with the molecular formula C11H23N3O5S, a molecular weight of 309.39, and the following structural formula:



LEGUBETI contains 500 mg and 2.5 grams of acetylcysteine (equivalent to 948 mg and 4.74 grams of acetylcysteine lysine, respectively) and the inactive ingredient: povidone.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Acetylcysteine has been shown to reduce the extent of liver injury following acetaminophen overdose. Acetaminophen doses of 150 mg/kg or greater have been associated with hepatotoxicity. Its effectiveness depends on early oral administration, with benefit seen principally in patients treated within 16 hours of the overdose. Acetylcysteine probably protects the liver by maintaining or restoring the glutathione levels, or by acting as an alternate substrate for conjugation with, and thus detoxification of, the reactive metabolite of acetaminophen.

12.2 Pharmacodynamics

The exposure-response relationship and time course of pharmacodynamic response for the safety and effectiveness of acetylcysteine have not been fully characterized.

12.3 Pharmacokinetics

Absorption
After administration of a single oral dose of 1 gram of LEGUBETI (dissolved in 200 mL of caffeine-free diet cola, and an additional 100 mL of water to rinse the dosing cup) to 24 healthy adult subjects, the mean Cmax (CV%) was 2170.74 (46) ng/mL and mean (CV) AUCinf was 2647.82 (33) ng •hr/mL. The median (range) time to reach Cmax (Tmax) was 0.5 (0.5 to 2) hours.

Distribution
The protein binding for acetylcysteine ranges from 66% to 87 %.

Elimination

Metabolism

Acetylcysteine (i.e., N-acetylcysteine) undergoes extensive first pass metabolism and is postulated to form cysteine and disulfides (N,N-diacetylcysteine and N-acetylcysteine). Cysteine is further metabolized to form glutathione and other metabolites.

Excretion

After a single oral dose of [35S]-acetylcysteine 100 mg, between 13 to 38% of the total radioactivity administered was recovered in urine within 24 hours. In a separate study, renal clearance was estimated to be approximately 30% of total body clearance. In healthy subjects given a single oral dose of 1 gram of LEGUBETI, the mean (CV%) terminal plasma half-life (T1/2) was 3.30 (25%) hours.

Specific Populations

Hepatic Impairment

Following a 600 mg intravenous dose of acetylcysteine to subjects with mild (Child Pugh Class A, n=1), moderate (Child-Pugh Class B, n=4) or severe (Child-Pugh Class C; n=4) hepatic impairment and 6 healthy matched controls, mean T1/2 increased by 80%. Also, the mean CL decreased by 30% and the systemic acetylcysteine exposure (mean AUC) increased 1.6-fold in subjects with hepatic impairment compared to subjects with normal hepatic function. These changes are not considered to be clinically meaningful.

Renal Impairment

Hemodialysis may remove some of total acetylcysteine.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis
Carcinogenicity studies in laboratory animals have not been performed with acetylcysteine lysine (active ingredient in LEGUBETI) or with acetylcysteine.

Mutagenesis
Acetylcysteine lysine was negative in the bacterial reverse mutation (Ames) assay, the in vitro mouse lymphoma cell gene mutation assay, and the in vivo mouse micronucleus test. Acetylcysteine was negative in the Ames test.

Impairment of Fertility
In a fertility study of acetylcysteine in rats, intravenous administration of 1,000 mg/kg/day (0.3 times the recommended human oral dose based on body surface area) caused a profound reduction of fertility in females, which was correlated with morphological changes in oocytes and severe impairment of implantation (18 of 20 mated females had no implantations). The reversibility of this effect was not evaluated. No effects on fertility were observed in female rats at intravenous doses up to 300 mg/kg/day (0.1 times the recommended human oral dose based on body surface area), or in male rats at intravenous doses up to 1,000 mg/kg/day. Mating was unaffected in this study.

In a reproduction study of acetylcysteine, male rats were treated orally for 15 weeks prior to mating and during the mating period. A slight non-dose related reduction in fertility was observed at oral doses of 500 and 1,000 mg/kg/day (0.1 and 0.3 times the recommended human dose, respectively, based on body surface area).

No fertility studies have been performed with acetylcysteine lysine.

16 HOW SUPPLIED/STORAGE AND HANDLING

LEGUBETI (acetylcysteine) for oral solution is supplied as packets containing white powder.

500 mg acetylcysteine packets
• Carton of 10 packets (NDC 66277-319-10)
• Carton of 20 packets (NDC 66277-290-20)

2.5 grams acetylcysteine packets
• Carton of 10 packets (NDC 66277-320-10)
• Carton of 20 packets (NDC 66277-291-20)

Store at controlled room temperature of 20°C to 25°C (68°F to 77°F); excursions between 15°C and 30°C (59°F and 86°F) are permitted *[See USP Controlled Room Temperature]*. Protect from moisture. Store in original package until use.

Use prepared LEGUBETI solution within 1 hour after preparation *[See Dosage and Administration (2.3)]*.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Hypersensitivity Reactions
Advise patients that hypersensitivity reactions, including generalized urticaria may occur and to report any signs or symptoms to their healthcare provider immediately [*see Warnings and Precautions (5.1)*].

Manufactured by:
Galephar Pharmaceutical Research Inc.
Humacao, 00791, Puerto Rico, USA
Rev. FEB 2024

Patient Information
LEGUBETI™ (leg-u- beti)
(acetylcysteine)
for oral solution

What is LEGUBETI?
LEGUBETI is a prescription medicine used to prevent or lessen liver damage in people who have taken too much acetaminophen (overdose).

Before receiving LEGUBETI, tell your healthcare provider about all your medical conditions, including if you:

- have or have had bleeding in your esophagus (esophageal varices).
- have or have had stomach ulcers.
- are pregnant or plan to become pregnant. It is not known if LEGUBETI will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if LEGUBETI passes into your breast milk and may harm your baby. You and your healthcare provider should decide if you will take LEGUBETI or breastfeed.

Tell your healthcare provider about all the medicines you take including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I receive LEGUBETI?

- Take LEGUBETI exactly as your healthcare provider tells you to.
- Your healthcare provider will tell you how much LEGUBETI to take and when to take it. Do not stop taking LEGUBETI unless your healthcare provider tells you to.
- Your healthcare provider may change your dose if needed.
- LEGUBETI should be taken by mouth only.
- LEGUBETI should be dissolved in caffeine-free diet cola or other diet soft drinks before taking.
- Take LEGUBETI within 1 hour of preparation.

What are the possible side effects of LEGUBETI?
LEGUBETI may cause serious side effects, including:

- **allergic reactions**. Stop taking LEGUBETI and tell your healthcare provider right away if you have any signs and symptoms of an allergic reaction including rash, hives, itching, chest tightness, light headedness, swelling of your face, eyes, lips, tongue or throat, trouble swallowing or breathing.
- **risk of bleeding in your esophagus and stomach.**
  The most common side effects of LEGUBETI include nausea, vomiting, stomach problems, rash (with or without a fever).

These are not all the possible side effects of LEGUBETI.
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of LEGUBETI.
Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your pharmacist or healthcare provider for information about LEGUBETI that is written for health professionals.

What are the ingredients in LEGUBETI?
Active ingredient: acetylcysteine lysine
Inactive ingredients: povidone

Manufactured by: Galephar Pharmaceutical Research Inc Humacao, 00791, Puerto Rico, USA
For more information call 1-800-984-7536

This Patient Information has been approved by the U.S. Food and Drug Administration Approved: 02/2024