

# Endari (L-glutamine)



**NEW PRODUCT SLIDESHOW**

**MPR**

# Introduction

- **Brand name:** Endari
- **Manufacturer:** Emmaus Medical
- **Generic name:** L-glutamine
- **Pharmacological class:** Amino acid
- **Strength and Formulation:** 5g; per packet; oral powder
- **How supplied:** Packets—60
- **Legal Classification:** Rx

# Indications

- To reduce acute complications of **sickle cell disease**

# Dosage & Administration

- Mix each dose in 8oz (240mL) of cold or room temperature **drink** (eg, water, milk, apple juice) or 4–6oz of **food** (eg, applesauce, yogurt) prior to ingestion; complete dissolution not required

# Dosage & Administration

- **≥5yrs:**
  - <30kg: 5g twice daily
  - 30–65kg: 10g twice daily
  - >65kg: 15g twice daily

# Considerations for Special Populations

- **Pediatric:** <5yrs: not established
- **Pregnancy:** No available data in pregnant women to establish drug-associated risk
- **Nursing mothers:** Consider mother's need and potential adverse effects on child
- **Elderly:** Insufficient number of subjects aged  $\geq 65$ yrs to determine whether they respond differently

# Adverse Reactions

- Constipation
- Nausea
- Headache
- Abdominal pain
- Cough
- Pain in extremity
- Back pain
- Chest pain

# Mechanism of Action

- The pyridine nucleotides, NAD<sup>+</sup> and its reduced form NADH, play roles in regulating and preventing oxidative damage in RBCs
- L-glutamine may improve the NAD redox potential in sickle RBCs through increasing the availability of reduced glutathione



# Clinical Studies

- Efficacy of Endari was evaluated in a randomized, double-blind, placebo-controlled, multi-center trial (N=230) in patients with sickle cell anemia or sickle beta-thalassemia with 2 or more painful crises within 12 months prior to enrollment

# Clinical Studies

- Study patients received Endari or placebo for 48 weeks followed by 3 weeks of tapering
- Efficacy was demonstrated by a **reduction in the number of sickle cell crises** through Week 48 and prior to tapering among patients that received Endari vs placebo (3 vs 4, respectively)

# Clinical Studies

- Treatment with Endari also led to fewer hospitalizations due to sickle cell pain (2 vs 3) at Week 48, fewer cumulative days in hospital (6.5 vs 11), and a lower incidence of acute chest syndrome (8.6% vs 23.1%) compared to placebo, respectively
- The median time to first sickle cell crisis was longer in the Endari group vs placebo group (84 days vs 54 days, hazard ratio [HR] 0.69, 95% IC: 0.52, 0.93)

# Clinical Studies

- The recurrent crisis event time analysis suggested that over the 48-week period, the average cumulative crisis count was reduced by **25%** from the Endari group vs the placebo group
- For more clinical trial data, see full labeling

# New Product Monograph

- For more information view the product monograph available at:

<http://www.empr.com/endari/drug/34778/>