

**DATA SHEET****L-Citrulline Powder****Product Code**

C09 and C09-ROW.

**Active Ingredient**

L-Citrulline (base) Ph. Eur.

**Description of Product**

This product is supplied as a pure fine white powder.

**Presentation**

The product is supplied in a labelled white polypropylene container with a low density polyethene (LDPE) tamper evident closure containing 100g of free-flowing L-Citrulline powder.

**Storage**

Store below 25 °C in a dry place.

**Shelf Life**

23 months.

**Excipients of Known Effect**

None.

**Free-From Information**

This product is supplied as a pure powder containing no additional excipients.

**Therapeutic Indications**Used in the management of the hyperammonaemia associated with lysinuric protein intolerance (LPI)<sup>1</sup> and as an alternative to L-arginine in the management of hyperammonaemia due to urea cycle disorders (carbaryl phosphate synthase (CPS) and ornithine carbaryl transferase (OTC) deficiencies).<sup>2</sup>**Dosage**

Route	Age	Dose and frequency
Oral	Neonate and child	150 mg/kg daily in 3-4 doses, adjusted according to response. <sup>2</sup>

**Administration**Powder may be mixed with drinks or taken as a paste.<sup>2</sup>

### **Contraindications and Precautions**

L-Citrulline is an endogenous precursor of L-arginine. Do not use in arginase deficiency.<sup>2</sup>  
L-Citrulline is also not recommended for patients with Argininosuccinate lyase (ASL) and Argininosuccinate Synthetase (ASS) deficiencies as levels of citrulline are already elevated.<sup>3</sup>

### **Side-effects and Adverse Reactions**

None reported.

### **Mode of Action**

Provides a source of L-Arginine, which becomes an essential amino acid, in patients with severe CPS and OTC enzyme deficiencies.<sup>4</sup>

### **Pharmacokinetics**

L- Citrulline is converted to L-Arginine, thus preventing Arginine deficiency. Citrulline contributes one less nitrogen atom to the free amino acid pool than arginine thereby reducing waste nitrogen production.<sup>4</sup>

### **Interactions with other Medications**

No information available.

### **Pregnancy and Breastfeeding**

No information available.

### **Legal Category**

L-Citrulline Powder is an 'Unlicensed Medicine' within the meaning of the current legislation, governed by the Human Medicines Regulations 2012.

This publication is solely for the technical guidance of prescribers and dispensers of L-Citrulline Powder and must not be considered as a recommendation or endorsement for the clinical use of the product. The information provided in this publication may not be exhaustive or reflective of all the information in the public domain.

### **Transmissible Spongiform Encephalopathies**

All starting materials are certified as compliant with EMEA/410/01 (S.I. 2003/1680) for minimising the risk of BSE/TSE contamination.

### **References:**

1. Brayfield A (ed), Martindale: The Complete Drug Reference. *Citrulline* [online] London: Pharmaceutical Press. Available from <<http://www.medicinescomplete.com/> Arginine> (accessed on 16-Apr-2019).
2. Paediatric Formulary Committee (2019). *BNF for Children 2019-2020*. London: BMJ Group, Pharmaceutical Press, and RCPCH Publications. p. 636
3. Brayfield A (ed), Martindale: The Complete Drug Reference. *Arginine* [online] London: Pharmaceutical Press. Available from <<http://www.medicinescomplete.com/> Arginine> (accessed on 16-Apr-2019).
4. Berg JM, Tymoczko JL, Stryer L. *Biochemistry*. 5th edition. New York: W H Freeman; 2002. Section 23.4, Ammonium Ion is converted into urea in most terrestrial vertebrates. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK22450>

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