

LOARGYS Product acquisition



LOARGYS is available in a single-dose vial

Drug name/strength	10-digit NDC #	11-digit NDC #*
LOARGYS 2 mg/0.4 mL	81583-102-01	81583- 0 102-01

The number of LOARGYS vials needed is based on patient's actual body weight (kg) and the recommended starting dosage of LOARGYS (0.1 mg/kg). The calculated volume of LOARGYS is rounded to the nearest 0.1 mL. The maximum recommended dosage is 0.2 mg/kg once weekly.

*The product's NDC has been "zero-filled" to ensure creation of an 11-digit code that meets general billing standards. The zero-fill is indicated in bold.

LOARGYS is available through 2 distribution channels

Specialty pharmacy for LOARGYS

Orsini Specialty Pharmacy is the exclusive specialty pharmacy for LOARGYS

Pharmacy phone: 1-(844)-982-5691

Pharmacy fax: 1-(844)-982-5693

Email: patientcare@orsinihc.com

Buy and bill for LOARGYS

Morris & Dickson is the exclusive authorized distributor for LOARGYS

Phone: 1-(800)-388-3833

Email: LOARGYS@mdspecialtydist.com

No claim for reimbursement for free product or related medical procedures and services will be submitted to any payer, including Medicare and Medicaid; and no free product may be sold, traded, bartered, or distributed for sale. Any free product distributed through the There for Rare Patient Assistance Program is not contingent on any purchase obligations.



If you have questions about payer coverage or options, submit a Patient Enrollment Form and There for Rare will review your patient's benefits to determine what options may be viable.

There for Rare is a patient support program. Restrictions, limitations and/or eligibility requirements may apply.

IMPORTANT SAFETY INFORMATION

WARNING: HYPERSENSITIVITY REACTIONS INCLUDING ANAPHYLAXIS

See full prescribing information for complete boxed warning

Initiate LOARGYS in a healthcare setting with appropriate medical monitoring and support measures, including access to cardiopulmonary resuscitation equipment. If a severe hypersensitivity reaction (e.g., anaphylaxis) occurs, discontinue LOARGYS, and immediately initiate appropriate medical treatment, including use of epinephrine.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions Including Anaphylaxis: Life-threatening hypersensitivity reactions, including anaphylaxis, have occurred in patients treated with enzyme replacement therapies, including LOARGYS. Hypersensitivity reactions that were mild to moderate in severity occurred in 13% (6/48) of LOARGYS-treated subjects in clinical trials. Hypersensitivity reactions have included facial swelling, rash, flushing and dyspnea. The reactions generally occurred with the first few doses but may occur later in treatment.

Please see additional Important Safety Information on the following page and full [Prescribing Information](#).

Loargys® (pegzilarginase-nbln) delivery and storage considerations



Shipment of LOARGYS: LOARGYS is shipped in an insulated box with gel packs sufficient to keep its temperature at 2 °C to 8 °C (36 °F to 46 °F).



Delivery: Deliveries should be immediately inspected for damage, then opened, unpacked, and contents placed into a refrigerator. Promptly report any delivery damage to the distributor or specialty pharmacy.



Storage and Handling: To best protect the stability of LOARGYS, care should be taken to ensure consistent temperature control (2 °C to 8 °C, 36 °F to 46 °F), such as the use of temperature monitoring and alarm devices for deviations. Store in the original carton to protect from light, do not freeze or shake. Follow the instructions in the LOARGYS Prescribing Information for storage, handling, and preparation of LOARGYS.

For product damaged in shipment, please contact your distributor or specialty pharmacy.

Orsini Speciality Pharmacy phone number: **1-(844)-982-5691**

Morris & Dickson phone number: **1-(800)-388-3833**

IMPORTANT SAFETY INFORMATION (cont'd) WARNINGS AND PRECAUTIONS (cont'd)

Administration of LOARGYS should be supervised by a healthcare provider knowledgeable in the management of hypersensitivity reactions including anaphylaxis in a healthcare setting with appropriate medical monitoring and support measures. Premedication with an antihistamine and/or corticosteroid should be considered in patients who previously have developed a hypersensitivity reaction. If a severe hypersensitivity reaction (e.g., anaphylaxis) occurs, discontinue LOARGYS and immediately initiate appropriate medical treatment, including use of epinephrine. Consider the risks and benefits of re-administering LOARGYS in patients who have experienced a severe hypersensitivity reaction. Caution should be exercised upon rechallenge. Inform patients of the symptoms of life-threatening hypersensitivity reactions and to seek immediate medical attention should symptoms occur. If a mild or moderate reaction occurs, consider treatment with antihistamines and/or corticosteroids.

ADVERSE REACTIONS

The most common adverse reactions are vomiting, pyrexia, infusion associated reactions and constipation.

USE IN SPECIFIC POPULATIONS

Pregnancy: There are no available data on LOARGYS use in pregnant females to evaluate for a drug-associated risk of major birth defects, miscarriage or other adverse maternal or fetal outcomes.

Lactation: There is no data on the presence of LOARGYS in either human or animal milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for LOARGYS and any potential adverse effects on the breast-fed infant from LOARGYS or from the underlying maternal condition.

Pediatric: The safety and effectiveness of LOARGYS have been established for the reduction of plasma arginine in pediatric patients 2 years and older with ARG-1 D, in conjunction with dietary protein restriction. The safety and effectiveness of LOARGYS have not been established for the reduction of plasma arginine in pediatric patients aged less than 2 years with ARG-1 D.

Geriatric: Clinical studies of LOARGYS did not include subjects 65 years of age and older to determine whether they respond differently from younger adult subjects.

INDICATION

LOARGYS is an arginine specific enzyme indicated for the treatment of hyperargininemia in adult and pediatric patients 2 years of age and older with Arginase 1 Deficiency (ARG1-D), in conjunction with dietary protein restriction.

This indication is approved under accelerated approval based on reduction of plasma arginine. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Please see additional Important Safety Information on previous page and full [Prescribing Information](#).



Marketed by:
Immedica Pharma US Inc., Chicago, IL 60642

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