

DOSING EXAMPLES

The maximum OLPRUVA™ (sodium phenylbutyrate) for oral suspension dosage is 20 g per day taken with food

3 times/day OLPRUVA dosing examples

Patient BSA, m ²	Total Daily Dosage, g		Recommended Dosing Envelope Size
	Min	Max	
1.2	11.9	15.6	4 g or 5 g
1.3	12.9	16.9	4 g or 5 g
1.4	13.9	18.2	5 g or 6 g
1.5	14.9	19.5	5 g or 6 g
1.6	15.8	20	6 g or 6.67 g
1.7	16.8	20	6 g or 6.67 g
1.8	17.8	20	6 g or 6.67 g

4 times/day OLPRUVA dosing examples

Patient BSA, m ²	Total Daily Dosage, g		Recommended Dosing Envelope Size
	Min	Max	
1.2	11.9	15.6	3 g
1.3	12.9	16.9	3 g or 4 g
1.4	13.9	18.2	3 g or 4 g
1.5	14.9	19.5	3 g or 4 g
1.6	15.8	20	4 g or 5 g
1.7	16.8	20	4 g or 5 g
1.8	17.8	20	4 g or 5 g

5 times/day OLPRUVA dosing examples

Patient BSA, m ²	Total Daily Dosage, g		Recommended Dosing Envelope Size
	Min	Max	
1.2	11.9	15.6	2 g or 3 g
1.3	12.9	16.9	2 g or 3 g
1.4	13.9	18.2	2 g or 3 g
1.5	14.9	19.5	3 g
1.6	15.8	20	3 g or 4 g
1.7	16.8	20	3 g or 4 g
1.8	17.8	20	3 g or 4 g

6 times/day OLPRUVA dosing examples

Patient BSA, m ²	Total Daily Dosage, g		Recommended Dosing Envelope Size
	Min	Max	
1.2	11.9	15.6	2 g
1.3	12.9	16.9	2 g
1.4	13.9	18.2	2 g or 3 g
1.5	14.9	19.5	2 g or 3 g
1.6	15.8	20	2 g or 3 g
1.7	16.8	20	2 g or 3 g
1.8	17.8	20	3 g

Calculations performed with the Du Bois method¹: $BSA = 0.007184 \times \text{Height}^{0.725} \times \text{Weight}^{0.425}$

Find your patient's dose with the dosing calculator at OlpruvaHCP.com

Please see Important Safety Information on next page and full [Prescribing Information](#) for OLPRUVA.

OLPRUVA™
(sodium phenylbutyrate)
for oral suspension

Indication and Important Safety Information for OLPRUVA

OLPRUVA [ol proo vah] (sodium phenylbutyrate) for oral suspension

Indication

OLPRUVA is a nitrogen-binding agent indicated as adjunctive therapy to the standard of care, which includes dietary management, in the chronic management of adult and pediatric patients, weighing 20 kg or greater and with a body surface area (BSA) of 1.2 m² or greater, with urea cycle disorders (UCDs) involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS).

Limitation of Use

OLPRUVA is not indicated for the treatment of acute hyperammonemia, which can be a life-threatening medical emergency that requires rapidly acting interventions to reduce plasma ammonia levels.

Important Safety Information

Warnings and Precautions

Neurotoxicity of Phenylacetate: Increased exposure to phenylacetate, the major metabolite of OLPRUVA, may be associated with neurotoxicity in patients with UCDs. If neurotoxicity symptoms of vomiting, nausea, headache, somnolence, or confusion are present in the absence of high ammonia levels or other intercurrent illnesses, consider reducing the dose of OLPRUVA.

Hypokalemia: Renal excretion of phenylacetylglutamine may induce urinary loss of potassium. Monitor serum potassium during therapy and initiate appropriate treatment when necessary.

Conditions Associated with Edema: OLPRUVA contains 124 mg of sodium per gram of sodium phenylbutyrate, and the Mix-Aid contains 5 mg of sodium per packet. Calculate the total amount of sodium based on the patient's body surface area. If a patient develops new-onset edema or worsening edema while on treatment, discontinue administration of sodium phenylbutyrate and initiate appropriate therapy.

Drug Interactions

Valproic acid, haloperidol, or corticosteroids may increase plasma ammonia levels. Monitor ammonia levels closely. Probenecid may inhibit renal excretion of metabolites of OLPRUVA including phenylacetate and phenylacetylglutamine; monitor for potential neurotoxicity.

Use in Specific Populations

No studies with OLPRUVA have been conducted in subjects with renal or hepatic impairment. Monitor ammonia levels and in patients with hepatic impairment, it is recommended to start at the lowest dose that controls ammonia levels. Dose selection for elderly patients should be cautious, usually starting at the low end of the dosing range.

OLPRUVA should be used with caution in patients who are pregnant or planning to become pregnant. Report pregnancies to Acer Therapeutics Inc. at 1-833-657-7882. There are no data on the presence of OLPRUVA in human milk, the effects on the breastfed infant, nor the effects on milk production. This should be considered when assessing the mother's need for OLPRUVA.

Adverse Reactions

Most common adverse reactions (incidence \geq 3%) are amenorrhea or menstrual dysfunction (irregular menstrual cycles), decreased appetite, body odor and bad taste or taste aversion.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

This information is not comprehensive.

For additional information, please see full [Prescribing Information](#) for OLPRUVA.

Reference: 1. Du Bois D, Du Bois EF. Clinical calorimetry tenth paper: a formula to estimate the approximate surface area if height and weight be known. *Arch Intern Med.* 1916;17:863-871.



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OLPRUVATM
(sodium phenylbutyrate)
for oral suspension