Fax completed form to Navigator by Acer Therapeutics at 1-855-624-2566; Phone <u>1-833-OLPRUVA</u>. Visit <u>OlpruvaHCP.com</u> for <u>Prescribing Information</u>.





# **OLPRUVA Prescription Enrollment Form**

1. Patient Information (required)		
First Name: Middle Initial: L	ast Name: / / Date of Birth: / /	
Gender: O Male O Female Preferred Communication Lan		
Primary Phone Number: Secondary Phone Number:		
Best Time to Call (choose 1):   AM PM Email:		
Address:	City: State: ZIP Code:	
	If yes, which one?	
If patient is younger than 18 years:		
Caregiver First Name: Caregiver Last Na	me: Relationship to Patient:	
2. Insurance Information (required)		
☐ No insurance coverage  Primary Insurance (please attach copy of front & back of insurance card):	Secondary Incurance* (please attach copy of front & back of incurance card)	
Primary Insurance (please attach copy of front & back of insurance card).  Primary Insurance Provider:	Secondary Insurance* (please attach copy of front & back of insurance card):  Secondary Insurance Provider:	
Primary Insurance Provider	Secondary Insurance Provider	
Name of Insured:		
Policy Number: Group Number:		
Employer of Insured: Group Number:		
Prescription Drug Insurance* (please attach copy of front & back of insur		
	ance card): *If applicable.  Insurance Phone Number:	
Member 1D Number: Group 1D Number:	PCN Number:	
3. Prescription Information (required)		
Patient Body Surface Area (BSA):m² Patient Height:	cm Patient Weight: kg	
ICD-10 Diagnosis Code (choose 1): E72.29 (Carbamylphosphate synthe		
E72.24 (Ornithine transcarbamylase)  E72.25 (Citrumine Hall 7 AGS1)  E72.20 (Disorder of urea cycle metabolism, unspecified)		
Total Daily OLPRUVA Dosage: g/day (See the OLPRUVA <u>Dosing page</u> on OlpruvaHCP.com)		
Dosing Frequency (choose either TID or Other Dosing [on-label dosing is 3-6 times daily; however, dosing is determined by the prescriber]):		
○ TID: Take grams by mouth 3 times/day		
○ 2-g dose envelopes ○ 3-g dose envelopes ○ 4-g dose envelo	pes O 5-g dose envelopes O 6-g dose envelopes O 6.67-g dose envelopes	
Other Dosing: Take grams by mouthtimes/day	Quantity: 30-day supply or dose envelopes Refills:	
Dispensing Options (choose 1):		
O Dispense As Written/Brand Medically Necessary/Do Not Substitute/	May Substitute/Product Selection Permitted/	
No Substitution/DAW/May Not Substitute	Substitution Permissible	
Prescriber's Signature:	Prescriber's Signature:	
Print Name: Date:	Print Name: Date:	
CA, MA, NC, & PR: Interchange is mandated unless Prescriber writes		
ATTN: NY & IA providers, please submit electronic prescription.		
By signing above, I certify that: (1) the medication I prescribe is medically necessary; (2) I have obtained any required consent under federal and state law for the release of		
the patient's information on this form to Acer Therapeutics Inc. and its contractors and business partners for benefits verification, prior authorization, financial assistance and coordination of dispensing OLPRUVA; (3) I will comply with any and all state-specific and federal prescription requirements and understand non-compliance with		
these requirements could result in further outreach by the patient's specialty pharmacy; (4) I understand that the information I provide on this form, if signed by the		
patient, will be used by Acer Therapeutics Inc. and its contractors as authorized by the patient. I authorize: (1) Acer Therapeutics Inc. to forward the prescription above		
to the applicable pharmacy; (2) Acer Therapeutics Inc. and their partners on behalf of my patient to furnish any information on this form to his/her insurer.		
4. Prescriber Information (required; benefits verification will be shared with Prescriber)		
Practice Name:		
	t Name: Specialty:	
	State License Number:	
Office Contact:		
Address:	City: State: ZIP Code:	
Office Phone:	City State ZIF Code	

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### 5. Patient Authorization (required)

Patient First Name:	Patient Last Name:	
Primary Phone Number:		
Best Time to Call (choose 1):   AM   PM	Email:	
If patient is younger than 18 years:		
Caragiyar First Nama:	Caragivar Last Namo	Polationship to Patient:

My signature below certifies that I have read, understand, and agree to the Patient Authorization to release my/the patient's protected health information to Acer Therapeutics Inc., and companies working on their behalf, including vendors, other affiliates, and other service providers supporting Navigator by Acer Therapeutics (collectively, "OLPRUVA, Navigator by Acer Therapeutics Program Consent.") I am authorizing Acer Therapeutics Inc. and Navigator by Acer Therapeutics to provide me/the patient with additional support for patients and caregivers. By signing this Authorization, I authorize my/the patient's healthcare providers, health plans, and pharmacy providers to disclose my/the patient's personal health information, and personal identifiable information, including, but not limited to, information relating to my/the patient's medical condition, treatment, care management, and health insurance, as well as any information about my/the patient's prescriptions ("Personal Health Information") to Acer Therapeutics Inc. and its personnel, representatives, contractors, and affiliates (collectively, "Acer Therapeutics Inc.") in order for Acer Therapeutics Inc. and Navigator by Acer Therapeutics to provide product support services. I further authorize Acer Therapeutics Inc. to use and disclose my/the patient's Personal Health Information to third parties, including, but not limited to specialty pharmacies, health plans, insurance companies, customer relationship management organizations, third party affiliates, patient financial programs, laboratories and patient assistance programs for such product support services, including, but not limited to, (1) investigating insurance coverage, (2) fulfilling and coordinating delivery of medication, medication reminder communication (in the form of voice, text or email) and communicating with me by mail, email, text messaging or telephone about my/the patient's medical condition, treatment, care management, and health insurance, (3) reimbursement assistance, (4) referral to/eligibility evaluation for financial assistance programs, (5) marketing and market research programs and providing information on programs that the patient requests, (6) improving Navigator by Acer Therapeutics quality of operations, and (7) collecting, entering and maintaining health information in a database. I understand that my/the patient's Personal Health Information, once disclosed under this authorization, may no longer be protected by federal or state privacy laws and could be disclosed by Acer Therapeutics Inc. as well as other recipients of the information to others not identified in this Authorization. I understand that I may choose not to sign this Authorization and that my/the patient's treatment, payment, enrollment in a health plan, or eligibility for benefits, including my/the patient's access to therapy, is not conditioned on my signing this Authorization. I understand that I am entitled to a signed copy of this Authorization. I understand that I may cancel this Authorization at any time by mailing a letter requesting such cancellation to Navigator by Acer Therapeutics representatives, One Gateway Center, Suite 356, Newton, MA 02458, which will convey the cancellation of all marketing partners that have received the Authorization. I also understand, however, that any such cancellation will not apply to any information already used or disclosed based on this Authorization prior to receipt of the cancellation by Acer Therapeutics Inc. This Authorization expires ten (10) years from the date signed below, unless a shorter period is required by the law of the patient's state of residence, or the Authorization is canceled.

I authorize Acer Therapeutics Inc. to leave a message, including the prescription name OLPRUVA, if I am unavailable. 🔘 Yes 🔘 No		
I authorize Acer Therapeutics Inc. to opt me in to receive marketing communications and hereby agree to receive information on behalf of Navigator by Acer Therapeutics. I understand that message and data rates may apply to cell phone communications.		
Patient or Guardian/Legal Representative Signature:		
Print Name:	Date:	





## 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 m<sup>2</sup> 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**

<u>Neurotoxicity of Phenylacetate</u>: 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.

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

<u>Conditions Associated with Edema</u>: 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.

OLPRUVA: (sodium phenylbutyrate) for oral suspension

For additional information, please see full <u>Prescribing Information</u> for OLPRUVA at OlpruvaHCP.com.