

PATIENT INFORMATION
OLPRUVA™ (ol proo vah)
(sodium phenylbutyrate)
for oral suspension

What is OLPRUVA?

- OLPRUVA is a prescription medicine used along with certain therapy, including changes in diet, for the long-term management of adults and children weighing 44 pounds (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).
- Episodes of rapid increase of ammonia in the blood (acute hyperammonemia) may happen in people during treatment with OLPRUVA. OLPRUVA is not for the treatment of acute hyperammonemia, which can be life-threatening and requires emergency medical treatment.
- OLPRUVA is not approved in children weighing less than 44 pounds (20 kg) or in children weighing 44 pounds (20 kg) or greater with a BSA of less than 1.2 m².

Before taking OLPRUVA, tell your or your child's healthcare provider about all of your medical conditions, including if you:

- have heart problems
- have kidney or liver problems
- are pregnant or plan to become pregnant. It is not known if OLPRUVA will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if OLPRUVA passes into breastmilk. Talk to your healthcare provider about the best way to feed your baby during treatment with OLPRUVA.

Tell your healthcare provider about all the medicines you or your child take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Certain medicines may increase the level of ammonia in your blood or cause serious side effects when taken during treatment with OLPRUVA. Especially tell your healthcare provider if you or your child take:

- corticosteroids
- valproic acid
- haloperidol
- probenecid

Know the medicines you take. Keep a list of them to show your or your child's healthcare provider and pharmacist when you get a new medicine.

How should I or my child take OLPRUVA?

Read the detailed Instructions for Use that comes with OLPRUVA for information about the right way to prepare and take a dose of OLPRUVA.

- Take OLPRUVA exactly as prescribed by your healthcare provider.
- Your healthcare provider may change your dose if needed. Do not change your dose unless your healthcare provider tells you to.
- Your healthcare provider will prescribe OLPRUVA based on your or your child's weight.
- Take your OLPRUVA dose with food.
- If you miss a dose of OLPRUVA, take it as soon as possible that same day.
- **Do not** give or take OLPRUVA through a gastrostomy or nasogastric tube.

- If you take too much OLPRUVA, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of OLPRUVA?

OLPRUVA can cause serious side effects, including:

- **Nervous system problems (neurotoxicity).** Call your healthcare provider right away if you or your child get any of the following symptoms during treatment with OLPRUVA:
 - sleepiness
 - tiredness
 - lightheadedness
 - vomiting
 - nausea
 - headache
 - confusion
- **Low potassium levels in your blood (hypokalemia).** Your healthcare provider will monitor your blood potassium levels during treatment with OLPRUVA and treat if needed.
- **Conditions related to swelling (edema).** OLPRUVA contains salt (sodium), which can cause swelling from salt and water retention. Your healthcare provider will decide if OLPRUVA is right for you if you have certain medical conditions that cause edema, such as heart failure, liver problems or kidney problems.

The most common side effects of OLPRUVA include:

- absent or irregular menstrual periods
- decreased appetite
- body odor
- bad taste or avoiding foods that you ate prior to getting sick (taste aversion)

Your healthcare provider may do certain blood tests to check you or your child for side effects during treatment with OLPRUVA.

These are not all of the possible side effects of OLPRUVA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store OLPRUVA?

- Store OLPRUVA at room temperature between 68°F and 77°F (20°C and 25°C).
- **Keep OLPRUVA and all medicines out of the reach of children.**

General information about the safe and effective use of OLPRUVA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use OLPRUVA for a condition for which it was not prescribed. Do not give OLPRUVA to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about OLPRUVA that is written for health professionals.

What are the ingredients in OLPRUVA?

Active ingredient: sodium phenylbutyrate

Inactive ingredients: amino methacrylate copolymer, hypromellose, microcrystalline cellulose, polyethylene glycol 6000, silicon dioxide, and talc.



acert therapeutics

Manufactured for:
Acer Therapeutics Inc.

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For more information, go to www.OLPRUVA.com or call Acer Therapeutics Inc. at 1-844-600-2237.

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This Patient Information has been approved by the U.S. Food and Drug Administration.

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