

INSTRUCTIONS FOR USE
PHEBURANE® (FE bue rayne)
(sodium phenylbutyrate)
oral pellets

Read this Instructions for Use before taking PHEBURANE oral pellets and each time you get a refill. There may be new information. This Instructions for Use does not take the place of talking to your healthcare provider about your medical condition or treatment. Talk to your healthcare provider or pharmacist if you have any questions about how to take a dose of PHEBURANE.

This Instructions for Use contains information on how to measure and take PHEBURANE.

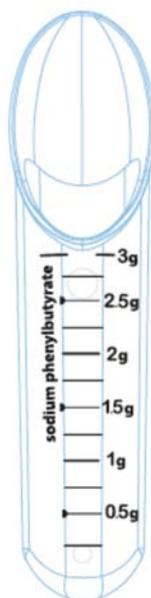


Figure A: Calibrated dosing spoon provided with PHEBURANE

Important information you need to know before taking PHEBURANE

- The total daily dose of PHEBURANE must be given in divided doses and taken with food (meal or snack). Your healthcare provider will tell you when to take PHEBURANE and the dose to take.
- Schedule PHEBURANE doses at the same time as eating a meal or snack.
- Only use the calibrated dosing spoon provided with PHEBURANE to measure the dose (See **Figure A**).

Supplies needed for measuring and taking PHEBURANE

- Bottle of PHEBURANE oral pellets.
- Calibrated dosing spoon provided with PHEBURANE.
- A drink such as water, fruit juices or protein-free infant formulas, **or** soft food, such as apple sauce or carrot puree. It is not recommended to use other foods to take your dose of PHEBURANE oral pellets.

Measuring PHEBURANE

Repeat Steps 1 through 3 throughout the day as prescribed by your healthcare provider to get the total daily dose.

Step 1

- Use the calibrated dosing spoon to measure the prescribed divided dose of PHEBURANE oral pellets (See **Figure A**).

The calibrated dosing spoon measures PHEBURANE oral pellets as grams (g) of sodium phenylbutyrate. The calibrated dosing spoon dispenses up to 3 g of sodium phenylbutyrate, in increments of 0.25 g.

- Pour the oral pellets directly into the calibrated dosing spoon until it reaches the black line for the prescribed dose of sodium phenylbutyrate in grams (See **Figure B**).

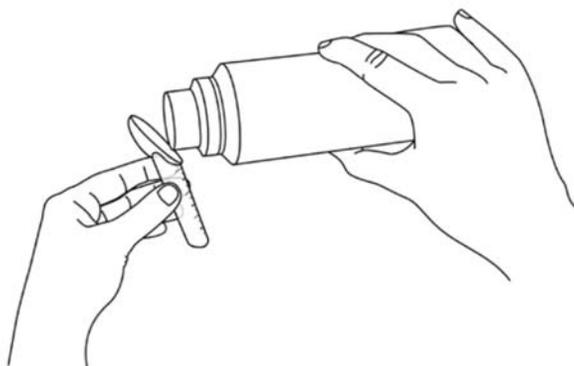


Figure B: Pour the PHEBURANE oral pellets directly into the calibrated dosing spoon.

Taking PHEBURANE

Step 2

- Tap the bottom of the calibrated dosing spoon 1 time on a hard surface to give a flat level of oral pellets and continue filling until you reach the prescribed dose.

Step 3

- Swallow PHEBURANE oral pellets with a drink such as water, fruit juices, or protein-free infant formulas.
- or
- Sprinkle PHEBURANE oral pellets onto a spoonful of apple sauce or carrot puree and swallow right away. It is important to swallow right away to prevent coating from dissolving.

Do not chew PHEBURANE oral pellets directly or mix PHEBURANE oral pellets into liquids.

If the prescribed divided dose is more than 3 grams, repeat Steps 1 through 3 to get the prescribed divided dose of sodium phenylbutyrate.

Storing PHEBURANE

- Store PHEBURANE at room temperature between 68°F and 77°F (20°C and 25°C).
- PHEBURANE comes in a child-resistant bottle. The bottle cap contains a desiccant to help keep PHEBURANE dry.
- Throw away (discard) any remaining PHEBURANE 45 days after first opening of the bottle.
- **Keep PHEBURANE and all medicines out of the reach of children.**

Disposing of PHEBURANE

- Throw away (dispose of) the bottle of PHEBURANE 45 days after first opening by dropping off the medicine at a drug take back site or following the steps below.
 - Mix medicine with an unappealing substance such as dirt, cat litter, or used coffee grounds
 - Place the mixture in a container such as a sealed plastic bag
 - Throw away the container in your trash at home, and
 - Delete all personal information on the prescription label of the empty medicine bottle, then throw away or recycle the empty bottle.
- Throw away (dispose of) used calibrated dosing spoon in the household trash.
- Do not use the calibrated dosing spoon to measure any other medicine.

If cleaning is necessary, rinse the calibrated dosing spoon with water and dry it completely.

To replace the calibrated dosing spoon, contact Medunik USA at 1-844-884-5520.

Distributed by: Medunik USA, Inc, 919 Conestoga Road, Bryn Mawr, PA 19010



PHEBURANE® is a registered trademark of Lucane Pharma.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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