Package leaflet: Information for the patient

PHEBURANE 350 mg/mL oral solution

sodium phenylbutyrate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist.
  This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What PHEBURANE oral solution is and what it is used for
2. What you need to know before you take PHEBURANE
3. How to take PHEBURANE
4. Possible side effects
5. How to store PHEBURANE
6. Contents of the pack and other information

1. What PHEBURANE is and what it is used for

PHEBURANE contains the active substance sodium phenylbutyrate which is used to treat patients with urea cycle disorders. These rare disorders are due to a deficiency of certain liver enzymes which are necessary to eliminate waste nitrogen in the form of ammonia.

Nitrogen is a building block of proteins, which are an essential part of the food we eat. As the body breaks down protein after eating, waste nitrogen, in the form of ammonia, accumulates because the body cannot eliminate it. Ammonia is especially toxic for the brain and leads, in severe cases, to reduced levels of consciousness and to coma.

PHEBURANE helps the body to eliminate waste nitrogen, reducing the amount of ammonia in your body. However PHEBURANE oral solution must be used along with a diet reduced in proteins, designed especially for you by the doctor and the dietician. You must follow this diet carefully.

2. What you need to know before you take PHEBURANE

Do not take PHEBURANE if you:
- are allergic to sodium phenylbutyrate or any of the other ingredients of this medicine (listed in section 6).
- are pregnant.
- are breast-feeding.

Warnings and precautions
Talk to your doctor or pharmacist before taking PHEBURANE if you:
- suffer from congestive heart failure (a type of heart disease where the heart cannot pump enough blood around the body) or a decrease in your kidney function.
- have decreased kidney or liver function, since PHEBURANE oral solution is eliminated from the body through the kidney and liver.

PHEBURANE will not prevent the occurrence of an acute excess of ammonia in the blood, a condition which usually constitutes a medical emergency. If this happens you will develop symptoms such as feeling sick (nausea), being sick (vomiting), confusion and will need to get urgent medical help.

If you need laboratory tests, it is important to remind your doctor that you are taking PHEBURANE oral solution, since sodium phenylbutyrate may interfere with certain laboratory test results (such as blood electrolytes or protein, or liver function tests).

In case of any doubt, ask your doctor or pharmacist.

Other medicines and PHEBURANE
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

It is especially important to tell your doctor if you are taking medicines containing:
- valproate (an antiepileptic medicine).
- haloperidol (used in certain psychotic disorders).
- corticosteroids (medicines that are used to provide relief for inflamed areas of the body).
- probenecid (for treatment of hyperuricaemia, high levels of uric acid in the blood, associated with gout).

These medicines may change the effect of PHEBURANE and you will need more frequent blood tests. If you are uncertain if your medicines contain these substances, you should check with your doctor or pharmacist.

Pregnancy and breast-feeding
Do not use PHEBURANE if you are pregnant, because this medicine can harm your unborn baby.

If you are a woman who could get pregnant, **you must use reliable contraception, during treatment with PHEBURANE.** Talk to your doctor for the details.

Do not use PHEBURANE if you are breast-feeding, because this medicine can pass into the breast milk and may harm your baby.

Driving and using machines
PHEBURANE oral solution is unlikely to affect your ability to drive and use machines.

PHEBURANE oral solution contains sodium
This medicine contains 124 mg (5.4 mmol) sodium (main component of cooking/table salt) in each g dose of sodium phenylbutyrate. This is equivalent to 6.2% of the recommended maximum daily dietary intake of sodium for an adult.
The maximum daily dose of this medicine contains 2.5 g sodium. This is equivalent to 125% of the recommended maximum daily dietary intake of sodium for an adult.
Talk to your doctor or pharmacist if you need 3 or more grams daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

PHEBURANE oral solution contains aspartame
This medicine contains 5.7 mg of aspartame per g dose of sodium phenylbutyrate. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

Blackcurrant flavour topping contains propylene glycol
This medicine contains 26.55 mg of propylene glycol per drop.

If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.

3. How to take PHEBURANE oral solution

Always take this medicine exactly as your doctor has told you.
Check with your doctor or pharmacist if you are not sure.

Dose
The daily dose of PHEBURANE oral solution will be based on your body weight or body surface and adjusted according to your protein tolerance and diet. You will need regular blood tests to determine the correct daily dose. Your doctor will tell you the amount of liquid you should take.

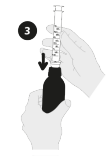
Method of administration
PHEBURANE oral solution should be taken with meals.
Use only the dosing syringe provided with PHEBURANE oral solution to measure a dose of PHEBURANE oral solution. Do not use othe devices/spoons/syringes to administer a dose. The syringe is ranging from 0.5 g to 3 g with 0.25 increments. The graduation of the dosing syringe reflects the grams of sodium phenylbutyrate. Follow the instructions below to administer PHEBURANE oral solution:

Administration for oral use

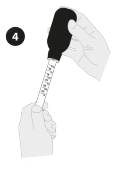
1. Open the bottle of PHEBURANE oral solution by pushing down on the cap and twisting to the left.

2. Take the CE marked dosing syringe with attached bottle adapter from the sachet.

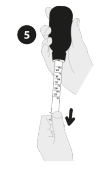
3. Place (push) the adapter in the neck of the bottle while the syringe is in the adapter.



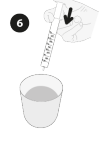
4. Invert the bottle.



5. Take the required quantity of PHEBURANE oral solution from the bottle (equivalent to the number of grams sodium phenyl butyrate as prescribed by your doctor) with use of the dosing syringe.



6. Take the dosing syringe with PHEBURANE oral solution out of the adapter and pour the quantity of PHEBURANE oral solution in the dosing syringe into a glass with minimum 20 ml water.



7. Close the bottle with PHEBURANE oral solution without removing the bottle adapter inserted in the neck of the bottle.

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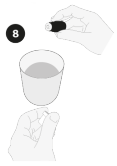
8. When using the pack **with toppings**, add **one drop** of the flavour topping of your like (blackcurrant or lemon-mint) to the content of the glass of water; swirl gently, and then drink (If one drop of flavour topping would not provide the taste intensity of your like, you could use 2 drops). When using the pack **without toppings,** swirl gently and drink



9. After each administration, wash the syringe with cold to lukewarm water only.

PHEBURANE oral solution must be taken with a special diet reduced in protein.

You should take PHEBURANE oral solution with each meal or feeding.
In small children this can be 4 to 6 times per day.

PHEBURANE oral solution can also be administered by nasogastric or gastrostomy tubes. PHEBURANE oral solution can be administered with tubes of a diameter of 2 mm (7-8 French) and larger. Use the provided oral syringe to measure your dose and follow the instructions below:

Preparation for nasogastric tube or gastrostomy tube administration

1. Follow Step 1 to Step 5 of the *Method of administration for oral use*;
2. The oral solution of Pheburane is ready-to use and no dilution is needed;
3. When used via nasogastric/gastrostomy **the flavour topping should not be added**;
4. Insert the tip of the syringe filled with the medicine onto the tip of the nasogastric/gastrostomy tube;
5. Use the plunger of the dosing syringe to administer the prescribed dose of PHEBURANE oral solution into the nasogastric/gastrostomy tube;
6. After each administration, the tube should be flushed once with the adequate volume of lukewarm water and allowed to drain.
   For adults, 20 ml of lukewarm water should be used.
   For children weighing less than 20 kg and neonates use 3 m of water.

You will need to take this medicine and to follow a diet throughout your life.

If you take more PHEBURANE oral solution than you should
Patients who have taken very high doses of sodium phenylbutyrate experienced:
- sleepiness, tiredness, light-headedness and less frequently confusion;
- headache;
- changes in taste (taste disturbances);
- decrease in hearing;
- disorientation;
- impaired memory;
- worsening of existing neurological conditions.

If you experience any of these symptoms, you should immediately contact your doctor or the nearest hospital emergency department for supportive treatment.

If you forget to take PHEBURANE oral solution
You should take a dose as soon as possible with your next meal.
Make sure that there are at least 3 hours between two doses. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If persistent vomiting occurs, you should contact your doctor immediately.

Very common side effects
(may affect more than 1 in 10 people)
irregular menstrual periods and stopping of menstrual periods in fertile women. If you are sexually active and your period stops altogether, do not assume that this is caused by PHEBURANE oral solution. If this occurs, please discuss it with your doctor, because the absence of your period may be caused by pregnancy (see 'Pregnancy and breast-feeding' section above) or by menopause.

Common side effects
(may affect more than 1 in 100 people)
changes in number of blood cells (red cells, white cells and platelets), changes in the amount of bicarbonate in the blood, reduced appetite, depression, irritability, headache, fainting, fluid retention (swelling), changes in taste (taste disturbances), stomach ache, vomiting, nausea, constipation, abnormal skin odor, rash, abnormal kidney function, weight gain, altered laboratory test values.

Uncommon side effects
(may affect more than 1 in 1,000 people)
deficiency in red blood cells due to failure of the bone marrow, bruising, altered heart rhythm, rectal bleeding, inflammation of the stomach, stomach ulcer, inflammation of the pancreas.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store PHEBURANE

Keep this medicine out of the sight and reach of children.

Do not use PHEBURANE oral solution after the expiry date which is stated on the carton and the bottle label after EXP. The expiry date refers to the last day of that month.

Once the PHEBURANE oral solution bottle is first open, you must use your medicine within 4 weeks of opening. The bottle should be discarded even if it is not empty.

Once the flavour bottle is first open, you must use it within 4 weeks of opening. The bottle should be discarded even if it is not empty.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information
There are 2 types of pack, namely a pack with and a pack without toppings
What PHEBURANE oral solution contains
- The active substance is sodium phenylbutyrate. Each mL of liquid contains 350 mg of sodium phenylbutyrate.
- The other ingredients are: purified water, aspartame (E951), sucralose (E955), glycerol (E422), hydroxyethylcellulose (E1525) (See section 2 "PHEBURANE oral solution contains aspartame").

The pack with toppings also contains
Flavour toppings:
- Blackcurrant flavour topping consisting of blackcurrant and mint flavouring, containing propylene glycol (E1520).
- Lemon-mint flavour topping consisting of lemon and mint flavouring.

What PHEBURANE oral solution looks like and contents of the pack
PHEBURANE oral solution is clear, colourless to pale yellow liquid.

Each pack contains:
- One amber glass bottle containing 100 mL of the oral solution and closed with a plastic child-resistant cap;
- One dosing syringe with ranging from 0.5 g to 3 g with 0.25 increments to measure the dose in grams of sodium phenylbutyrate;
- Bottle Adapter,

The pack with toppings also contains
- One amber glass bottle containing 3 mL of lemon-mint flavour topping,
- One amber glass bottle containing 3 mL of blackcurrant flavour topping.

Marketing Authorisation Holder and Manufacturer
Eurocept International BV - Trapgans 5 - 1244 RL Ankeveen
The Netherlands

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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