Package leaflet: Information for the user

AMMONAPS 500 mg tablets
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 AMMONAPS is and what it is used for

AMMONAPS is prescribed to patients with urea cycle disorders. Patients with these rare disorders have a deficiency of certain liver enzymes and are therefore unable to eliminate nitrogen waste. Nitrogen is a building block of proteins, because of this, there is a build up of nitrogen in the body after eating protein. Nitrogen waste, in the form of ammonia, is especially toxic for the brain and leads, in severe cases, to reduced levels of consciousness and to coma.

AMMONAPS helps the body to eliminate nitrogen waste, reducing the amount of ammonia in your body.

2. What you need to know before you take AMMONAPS

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

Warnings and precautions
Talk to your doctor before taking AMMONAPS
- if you have difficulty swallowing. AMMONAPS tablets can get stuck in the oesophagus and cause ulcers. If you have difficulty swallowing it is recommended to use AMMONAPS granules instead.
- if you suffer from heart failure, a decrease in your kidney function or other diseases, where the retention of the sodium salt contained in this medicine, may make your condition worse.
- if you have decreased kidney or liver function, since AMMONAPS is eliminated from the body through the kidney and liver.

- when given to small children, since they may not be able to swallow the tablets and may choke. It is recommended to use AMMONAPS granules instead.

AMMONAPS must be combined with a diet reduced in proteins designed especially for you by the doctor and the dietician. You must follow this diet carefully.

AMMONAPS does not completely prevent the occurrence of an acute excess of ammonia in the blood and is not appropriate for treating such a condition, which is a medical emergency.

If you require laboratory tests, it is important to remind your doctor that you are taking AMMONAPS, since sodium phenylbutyrate may influence certain laboratory test results.

Other medicines and AMMONAPS
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:
- valproic acid (an antiepileptic drug),
- haloperidol (used in certain psychotic disorders),
- corticosteroids (cortisone-like medicines that are used to provide relief for inflamed areas of the body),
- probenecid (for treatment of hyperuricemia associated with gout).

These medicines may change the effect of AMMONAPS and you will need more frequent blood controls. 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 AMMONAPS 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 AMMONAPS.
Do not use AMMONAPS if you are breast-feeding, because this medicine can pass into the breast-milk and harm your baby.

Driving and using machines
No studies on the effects on the ability to drive and use machines have been performed.

AMMONAPS contains sodium
Each AMMONAPS tablet contains 62 mg of sodium.

Talk to your doctor or pharmacist if you need 6 or more tablets daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

3. How to take AMMONAPS

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

Dosage
The daily dose of AMMONAPS will be calculated from your protein tolerance, diet and body weight or body surface. You will need regular blood tests to determine the correct daily dose. Your doctor will tell you how many tablets you should take.

Method of administration

You should take AMMONAPS by mouth in equally divided doses with each meal (for example three times per day). You should take AMMONAPS with a large volume of water.

AMMONAPS must be taken with a special diet reduced in protein.

AMMONAPS tablets should not be given to children who are not able to swallow tablets. It is recommended that AMMONAPS granules are used instead.

You will need to have treatment and to follow a diet throughout your life, unless you have a successful liver transplantation.

If you take more AMMONAPS than you should
Patients who have taken very high doses of AMMONAPS 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 AMMONAPS
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.

The frequency of possible side effects is listed below.

Very common:	Affects more than 1 user in 10
Common:	Affects 1 to 10 users in 100
Uncommon:	Affects 1 to 10 users in 1,000
Rare:	Affects 1 to 10 users in 10,000
Very rare:	Affects less than 1 user in 10,000
Not known:	Frequency cannot be estimated from the available data

Very common side effects: irregular menstrual periods and cessation of menstrual periods.
If you are sexually active and your period stops altogether, do not assume that this is caused by AMMONAPS. 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).

Common side effects: changes in number of blood cells (red cells, white cells and platelets), reduced appetite, depression, irritability, headache, fainting, fluid retention (swelling), changes in taste (taste disturbances), pain in the abdomen, vomiting, nausea, constipation, skin odour, rash, abnormal kidney function, weight gain, altered laboratory test values.

Uncommon side effects: deficiency in red blood cells due to bone marrow depression, bruising, altered heart rhythm, rectal bleeding, stomach irritation, stomach ulcer, inflammation of the pancreas.

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

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:

United Kingdom
Yellow Card Scheme
Website: 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 AMMONAPS

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

Do not use this medicine 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.

Do not store above 30°C.

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

What AMMONAPS contains

- The active substance is sodium phenylbutyrate.
  Each tablet of AMMONAPS contains 500 mg of sodium phenylbutyrate.
- The other ingredients are microcrystalline cellulose, magnesium stearate and colloidal anhydrous silica.

What AMMONAPS looks like and contents of the pack
AMMONAPS tablets are off-white, oval and embossed with "UCY 500".

The tablets are packaged in plastic bottles with child-resistant caps. Each bottle contains 250 or 500 tablets.

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