

Package leaflet: Information for the user

Potassium para-aminobenzoate 3 g Powder Sachets

Potassium para-aminobenzoate

(referred to as 'Potassium para-aminobenzoate Powder' in the rest of this leaflet)

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 Potassium para-aminobenzoate Powder is and what it is used for
2. What you need to know before you take Potassium para-aminobenzoate Powder
3. How to take Potassium para-aminobenzoate Powder
4. Possible side effects
5. How to store Potassium para-aminobenzoate Powder
6. Contents of the pack and other information

1. WHAT POTASSIUM PARA-AMINOBENZOATE POWDER IS AND WHAT IT IS USED FOR

The active ingredient in Potassium para-aminobenzoate Powder is potassium para-aminobenzoate. It is used in the treatment of Peyronie's disease (the growth of fibrous plaques in the soft tissue of the penis) and scleroderma (excessive deposits of collagen in the skin or other organs).

Potassium para-aminobenzoate is an antifibrosis agent, which acts by increasing oxygen uptake by the tissues.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE POTASSIUM PARA-AMINOBENZOATE POWDER

Do not take Potassium para-aminobenzoate Powder:

- if you are allergic to potassium para-aminobenzoate or other substances with similar chemical structure (e.g. benzocaine, procaine, ethyl parahydroxybenzoate) or any of the other ingredients of this medicine (listed in section 6)
- if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Potassium para-aminobenzoate Powder
- if you have kidney disease
- if you have a raised level of potassium in your blood (each sachet contains 669 mg potassium)
- if you are taking sulfonamides or combinations of sulfonamides with other antibiotics (e.g. sulfamethoxazole, sulfadimidine or co-trimoxazole)
- if you have severe liver damage

Warnings and precautions

You may need to stop taking Potassium para-aminobenzoate Powder for a while if you are not eating enough food (e.g. if you are fasting, have anorexia or are feeling sick). This is to reduce the risk of your blood sugar levels falling too low (see section 4).

Your condition will need to be carefully monitored by your doctor to ensure you do not become oversensitive to the medication, in which case treatment with Potassium para-aminobenzoate will be stopped. Symptoms of this include fever, rash and tiredness.

Furthermore, your doctor will regularly monitor your liver function. In case of elevated liver function tests, treatment with Potassium para-aminobenzoate Powder will be stopped.

Talk to your doctor or pharmacist before taking Potassium para-aminobenzoate Powder: Special caution is required,

- if you notice any of the symptoms related to these serious skin reactions described in section 4, stop using Potassium para-aminobenzoate Powder and seek medical attention immediately
- if you have kidney problems or any other condition that may cause high blood levels of potassium, Potassium para-aminobenzoate Powder should be used with caution
- if you experience symptoms possibly indicative of an increased potassium level in your blood while or after taking Potassium para-aminobenzoate Powder, please advise your doctor accordingly. Such symptoms include for example muscle pain or tightness, muscle weakness with reduced muscle tone, weakness, a tingling, pricking, chilling, burning or numb sensation of the skin, an awareness of an abnormal or slow heartbeat, or rapid breathing
- if you have a liver disorder or disease - your doctor will monitor your liver function
- if you experience symptoms possibly indicative of a liver disorder while or after taking Potassium para-aminobenzoate Powder, please advise your doctor immediately. Such symptoms include for example nausea, vomiting, loss of appetite, fever, a change of your urine colour or a yellowish or greenish staining of your skin and/or eyes

Children and adolescents

Potassium para-aminobenzoate Powder is not recommended for the use in children and adolescents.

Other medicines and Potassium para-aminobenzoate Powder

Please check with your doctor if you are taking any of the following medicines before taking Potassium para-aminobenzoate Powder:

- medicines known as sulfonamide antibiotics, e.g. co-trimoxazole or sulfadimidine
- methotrexate, a medicine used to treat cancer, arthritis and psoriasis
- digoxin, or any other cardiac glycoside, used to treat heart failure
- medicines known as aldosterone antagonists, e.g. eplerenone, spironolactone, used to treat high blood pressure and certain liver and kidney problems
- medicines known as potassium-sparing diuretics, e.g. amiloride, triamterene, used to treat high blood pressure and certain heart diseases
- medicines known as ACE-inhibitors, e.g. ramipril, lisinopril, enalapril, used to treat high blood pressure and certain heart and kidney problems
- medicines known as beta blockers, e.g. atenolol, bisoprolol, metoprolol, propranolol, used to treat high blood pressure and certain heart problems
- medicines known as non-steroidal anti-inflammatory drugs, e.g. ibuprofen, naproxen, diclofenac, used to treat pain, certain inflammatory conditions and fever
- medicines known as angiotensin receptor blockers or sartans, e.g. candesartan, irbesartan, losartan, valsartan, used to treat high blood pressure and heart failure

- medicines known as calcineurin inhibitors, e.g. ciclosporin or tacrolimus, used to treat certain autoimmune diseases like rheumatoid arthritis, psoriasis or atopic dermatitis, and to prevent transplant rejection after organ transplantation
- medicines known as penicillin antibiotics, e.g. phenoxymethylpenicillin, amoxicillin or flucloxacillin
- pentamidine, a medicine used to treat certain parasite infections
- ketoconazole, a medicine used to treat certain fungal infections
- medicines known as heparin and heparin derivatives, e.g. enoxaparin, dalteparin, tinzaparin, used to prevent formation of blood clots (thrombosis)
- potassium supplements and other medicinal products containing high potassium amounts

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without a prescription.

Potassium para-aminobenzoate Powder with food and drink

Always take Potassium para-aminobenzoate Powder with food, dissolving the powder in cold water or fruit juice. If you do not, there is a risk that you may feel slightly sick.

If, for any reason, you are not eating, or are just eating very small amounts, it is advisable that you stop taking Potassium para-aminobenzoate Powder until you start eating normally again. It is possible that if you do not interrupt treatment the levels of sugar in your blood may become too low and you may feel unwell.

In the elderly, the low blood sugar that may occur during periods of low food intake may be more difficult to recognise and may cause more neurological symptoms.

Pregnancy and breast feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Potassium para-aminobenzoate Powder should not affect your ability to drive or operate machinery. However, if you feel confused, sleepy or weak whilst taking your medicine do not drive or operate machinery until these symptoms have gone.

3. HOW TO TAKE POTASSIUM PARA-AMINOBENZOATE POWDER

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

The powder should be dissolved in cold water or fruit juice, to make it more pleasant to take, and drunk during mealtimes.

The recommended dose is 12 g a day. This is the equivalent of 4 sachets a day.

The dosage should be spread throughout the day as evenly as possible, to maintain the level of medicine in your system, **making sure you swallow the medicine with food**. Potassium para-aminobenzoate Powder should be taken for as long as your doctor has recommended.

Use in children and adolescents

Potassium para-aminobenzoate Powder is not recommended for use in children and adolescents.

If you take more Potassium para-aminobenzoate Powder than you should

If you take too much Potassium para-aminobenzoate Powder, or somebody else accidentally swallows Potassium para-aminobenzoate Powder, contact your doctor or the nearest hospital casualty department immediately.

Treatment for overdose will depend on the symptoms that are shown.

If you forget to take Potassium para-aminobenzoate Powder

If you miss a dose, wait until the next time you should take Potassium para-aminobenzoate Powder and take it as normal. 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.

Stop using Potassium para-aminobenzoate Powder and seek medical attention immediately if you notice any of the following symptoms:

- widespread rash, high body temperature and enlarged lymph nodes (drug reaction with eosinophilia and systemic symptoms; DRESS syndrome or drug hypersensitivity syndrome).
- allergic reactions, including severe rash or rash accompanied by raised liver enzymes, fever, general malaise, fatigue, muscle pain, blisters, oral lesions, swelling of the skin.
- intense hunger, shaking, feeling nervous, anxious or confused, sweating, dizziness or feeling light-headed, sleepiness, difficulty speaking or weakness. These symptoms may be caused by low levels of sugar in your blood (hypoglycaemia).

Other possible side effects:

Common (may affect up to 1 in 10 people)

- nausea (feeling sick), vomiting (being sick), loss of appetite, stomach discomfort, diarrhoea
- fever, chills

Uncommon (may affect up to 1 in 100 people)

- skin rash (including widespread rash, eczema, skin inflammation, chills), itching
- raised levels of liver enzymes (your doctor may arrange for you to have a blood test to check this)

Rare (may affect up to 1 in 1,000 people)

- inflammation of the liver (hepatitis)

Not known (frequency cannot be estimated from the available data)

- DRESS syndrome or drug hypersensitivity syndrome
- reduced levels of blood sugar (hypoglycaemia)
- drug-induced liver injury and hepatic failure

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via 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 of the safety of this medicine.

5. HOW TO STORE POTASSIUM PARA-AMINOBENZOATE POWDER

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. The expiry date refers to the last day of that month.

Do not store above 25 °C.

Store in the original packaging.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Potassium para-aminobenzoate Powder contains

The active substance is potassium para-aminobenzoate. Each sachet contains 3 g of the active ingredient.

There are no other ingredients.

What Potassium para-aminobenzoate Powder looks like and contents of the pack

Potassium para-aminobenzoate Powder is a white/off-white powder contained in a foil laminate sachet.

Each pack contains 40 sachets.

Marketing Authorisation Holder

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Hertford, SG13 7NN, United Kingdom

Manufacturer

CHEPLAPHARM Arzneimittel GmbH
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For information about this medicine, contact the medical information department via email: medinfo@neonhealthcare.com.

Product Licence Number: PL 45043/0044

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