SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Potaba 3 g Powder Sachets

Potassium para-aminobenzoate 3 g Powder Sachets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains 3 g potassium para-aminobenzoate.

3 PHARMACEUTICAL FORM

Powder for oral solution

Each sachet contains 3 g white/off-white powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Potassium para-aminobenzoate 3 g powder is indicated for the treatment of Peyronie's disease and scleroderma in adults.

4.2 Posology and method of administration

Posology

One sachet containing 3 g Potassium para-aminobenzoate powder should be taken orally, four times daily.

Paediatric population

The safety of Potassium para-aminobenzoate 3 g powder in children aged 0 to 18 years has not been established. No data are available.

Method of administration

For oral use.

The contents of one sachet should be dissolved in cold water or fruit juice and taken orally with food.

4.3 Contraindications

- Hypersensitivity to the active substance potassium para-aminobenzoate, para-substituted aromatic amines (e. g. benzocaine, procaine, ethyl parahydroxybenzoate) or to any of the excipients listed in section 6.1.
- Renal insufficiency (GFR < 45 ml/min).
- Hyperkalaemia (each sachet contains 669 mg potassium).
- Potassium para-aminobenzoate 3 g powder should not be given to patients taking sulphonamides as these medicinal products will be inactivated by potassium para-aminobenzoate (see section 4.5).
- Severe liver damage.

4.4 Special warnings and precautions for use

Hypersensitivity reactions

Potassium para-aminobenzoate 3 g powder must be discontinued immediately if signs or symptoms of hypersensitivity reactions develop (including, but not limited to, severe rash or rash accompanied by raised liver enzymes, fever, general malaise, fatigue, muscle pain, blisters, oral lesions, oedema and eosinophilia) and must not be restarted.

Severe cutaneous adverse reactions

Severe cutaneous adverse reactions (SCARs) manifesting as drug reactions with eosinophilia and systemic symptoms (DRESS), which can be life-threatening or fatal, have been reported in association with Potassium para-aminobenzoate 3 g powder treatment. At the time of prescription, patients should be advised of the signs and symptoms and monitored closely for skin reactions.

If signs and symptoms suggestive of this reaction appear, Potassium para-aminobenzoate 3 g powder should be withdrawn immediately.

If the patient has developed DRESS with the use of Potassium para-aminobenzoate 3 g powder, treatment with Potassium para-aminobenzoate 3 g powder must not be restarted in this patient at any time.

Food intake

Treatment with Potassium para-aminobenzoate 3 g powder should be interrupted during periods of low food intake (e.g. during fasting, anorexia, nausea). This is to avoid the possible development of hypoglycaemia. (see section 4.8).

Hyperkalaemia

In patients with impaired renal function or other diseases like diabetes mellitus, cardiovascular diseases, congestive heart failure, hypoaldosteronism and pseudohypoaldosteronism and/or in case of concomitant treatment with medicinal products that can increase the serum potassium level (see section 4.5), Potassium para-aminobenzoate 3 g powder should be used with caution because of the risk of hyperkalaemia.
Before start of treatment with Potassium para-aminobenzoate 3 g powder, an anamnestic survey of pre-existing hyperkalaemia risk factors including an initial serum potassium determination should be performed for all patients. For patients with an increased risk of hyperkalaemia, serum potassium should be measured at least monthly or at closer intervals depending on risk assessment and monitoring requirements due to other risk factors. For patients with an increased initial serum potassium level, the underlying cause should be identified insofar as possible and serum potassium levels should be normalised before start of treatment with Potassium para-aminobenzoate 3 g powder. For these patients, monitoring after start of therapy should also be performed monthly until long-term normal serum potassium levels are established. After that and for all other patients, monitoring is recommended at least quarterly.

Furthermore, serum potassium should be measured promptly for patients who report symptoms possibly indicative of hyperkalaemia such as muscle pain or tightness, flaccid paralysis, weakness, paraesthesia, nausea, vomiting, palpitations, bradycardia or tachypnoea.

Liver dysfunction

Hepatotoxic effects have been observed for Potassium para-aminobenzoate 3 g powder and were reported as hepatitis (various specifications), drug-induced liver injury or (acute) hepatic failure depending on results of diagnostic investigations, time course of drug use and liver disorder and other accompanying symptoms such as nausea, pyrexia, chromaturia or jaundice. For all patients who take Potassium para-aminobenzoate 3 g powder, regular (at least every 4 weeks) liver function tests must be performed (transaminases, gamma-GT, ALP, LDH, bilirubin). If elevated liver function tests or symptoms indicative of a liver disorder are observed, Potassium para-aminobenzoate 3 g powder must be discontinued immediately.

4.5 Interaction with other medicinal products and other forms of interaction

Sulfonamides will be inactivated by Potassium para-aminobenzoate 3 g powder since aminobenzoate is preferentially taken up by bacteria.

Methotrexate is displaced from plasma protein binding by aminobenzoate. Subsequently, plasma levels of methotrexate may increase if administered together with Potassium para-aminobenzoate 3 g powder.

The potassium in Potassium para-aminobenzoate 3 g powder can reduce the effect of concomitant cardiac glycosides.

Potassium levels may further increase with concomitant use of aldosterone antagonists, potassium-sparing diuretics, ACE inhibitors, beta blockers, non-steroidal anti-inflammatory drugs, angiotensin receptor blockers, calcineurin inhibitors, penicillins, pentamidine, ketoconazole, digoxin, heparin, potassium supplements and other medicinal products containing high potassium amounts.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no or limited amount of data from the use of potassium para-aminobenzoate in pregnant women.

Potassium para-aminobenzoate 3 g powder is not recommended during pregnancy.

Breastfeeding

It is unknown whether potassium para-aminobenzoate/metabolites are excreted in human milk.

A risk to the newborns/infants cannot be excluded.

Fertility

There are no or limited amount of data on the effects of potassium para- aminobenzoate on fertility.

4.7 Effects on ability to drive and use machines

Potassium para-aminobenzoate 3 g powder has no or negligible influence on the ability to drive and use machines. If patients experience confusion, lethargy or weakness they should not drive until such symptoms have fully reversed.

4.8 Undesirable effects

The following convention has been utilised for the classification of undesirable effects:

Very common (≥1/10), common (≥1/100, <1/10), uncommon (≥1/1,000, <1/100), rare (≥1/10,000, <1/1,000), very rare (<1/10,000), not known (cannot be estimated from the available data).

Drug reaction with eosinophilia and systemic symptoms (DRESS) has been reported in association with Potassium para-aminobenzoate 3 g powder treatment.

Immune system disorders

Not known: hypersensitivity reactions, including immunoallergic hepatitis (characterised by fever, rash, oedema, arthralgia/myalgia, elevated liver enzymes) (see section 4.4.)

Metabolism and nutrition disorders

Not known: hypoglycaemia (see section 4.4)

Gastrointestinal disorders

Common: nausea, vomiting, anorexia, stomach discomfort, diarrhoea

Hepatobiliary disorders

Uncommon: elevated liver enzymes (e.g. transaminases, gamma-GT, ALP, LDH)

Rare: hepatitis

Not known: drug-induced liver injury, hepatic failure

Skin and subcutaneous tissue disorders

Uncommon: skin rash (exanthema, eczema, dermatitis, urticaria), pruritus

Not known: Drug reaction with eosinophilia and systemic symptoms (DRESS)

General disorders and administration site conditions

Common: pyrexia, chills

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

No particular problems are expected following overdose with Potassium para-aminobenzoate 3 g powder. Symptomatic and supportive therapy should be given as appropriate.

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other dermatological preparations, Other dermatologicals, ATC code: D11AX23

Mechanism of action

Potassium para-aminobenzoate is considered a member of the Vitamin B complex. Small amounts are found in cereal, eggs, milk and meats. Detectable amounts are normally present in human blood, spinal fluid, urine and sweat. The pharmacological action of this chemical has

not been clearly established, but it has been suggested that the antifibrosis activity of potassium para-aminobenzoate is brought about by the drug increasing oxygen uptake at the tissue level. Fibrosis is believed to occur from either too much serotonin or too little monoamine oxidase activity over a period of time. The activity of monoamine oxidase is dependent on an adequate oxygen supply. By increasing oxygen supply at tissue level potassium para-aminobenzoate enhances monoamine oxidase activity thereby preventing or bringing about regression of fibrosis.

5.2 Pharmacokinetic properties

Absorption

Aminobenzoate is well absorbed after oral administration.

Oral administration of 3 g Potassium para-aminobenzoate to healthy volunteers resulted in maximum plasma levels of 29-74 μg/mL after 41-90 min. followed by rapid decrease to less than 10 μg/mL after 4 h.

Elimination

Potassium and conjugated aminobenzoate are eliminated by the kidney.

5.3 Preclinical safety data

In-vitro bacterial tests with para-aminobenzoate revealed no mutagenic potential. There are no long-term tests for carcinogenic potential. Adequate reproductive toxicity tests are not available for potassium para-aminobenzoate. In limited studies in pregnant rats, oral administration of 50 mg/kg/day para-aminobenzoate reduced foetal weights. In animal experiments, para-aminobenzoate crosses the placenta.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None in this presentation.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

5 years.

6.4 Special precautions for storage

Do not store above 25 ºC.

Store in the original packaging.

6.5 Nature and contents of container

Cardboard outer containing 40 foil laminate sachets.

6.6 Special precautions for disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Neon Healthcare Ltd.

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Hertford

SG13 7NN

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 45043/0044

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28/04/1981 / 16/01/2004

10 DATE OF REVISION OF THE TEXT

10/11/2022