

PRESCRIBING INFORMATION

NEPHROTRANS® 500MG GASTRO-RESISTANT CAPSULES

Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

Adverse events should be reported. Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to MEDICE UK on 020 4582 2845, pv-uk@medice.co.uk

Further information about this product, including adverse reactions, precautions, contraindications, and method of use can be found at <https://www.medicines.org.uk/emc>

ACTIVE INGREDIENT: Sodium hydrogen carbonate

INDICATIONS: Treatment of metabolic acidosis and for maintenance treatment against recurrence of metabolic acidosis in adults with chronic renal impairment.

DOSAGE and ADMINISTRATION: Dosage is based on the severity of metabolic acidosis from results of blood gas analysis or determination of serum bicarbonate. Blood pH level below 7.2 requires correction of acidosis by infusion. Mean daily dosage is 3 to 5 g sodium hydrogen carbonate (equivalent to 40-65 mg sodium hydrogen carbonate per kg body weight per day), achieved by taking 6 to 10 capsules.

ADMINISTRATION: Swallow whole throughout the day with sufficient liquid. Not to be taken without medical supervision for prolonged periods, as there is a possibility for the development of hypernatremia or alkalosis. The safety and efficacy of Nephrotrans 500 mg in children and adolescents has not been established.

CONTRAINDICATIONS: Hypersensitivity to the active substance, soya, peanuts, or excipients. Metabolic alkalosis, hypokalemia, hypernatraemia, low sodium diet.

SPECIAL WARNINGS AND PRECAUTIONS: Monitor effect (by pH measurement, standard bicarbonate, alkali reserve) and plasma electrolytes (especially sodium, potassium and calcium) initially at intervals of at least 1-2 weeks especially at higher doses and then regularly during long term treatment. Further dosing should be determined based on the outcome of these checks. Hyperalkalinity can be corrected by a dose reduction. Caution is required in hypoventilation, hypocalcaemia and hyperosmolar conditions. Nephrotrans 500 mg contains 137 mg sodium per capsule; maximum daily dose (10 capsules) represents 68% of the WHO recommended maximum daily sodium intake. This should be taken into account for those on a low salt diet. Nephrotrans 500 mg contains 50 mg sorbitol per capsule and should not be taken by patients with rare hereditary problems of fructose intolerance (HFI).

INTERACTIONS: May affect absorption and excretion of weak acids and bases (e.g. sympathomimetics, anticholinergics, tricyclic antidepressants, barbiturates, H₂ antagonists, captopril and quinidine) due to the increase in pH levels in the stomach and intestines. Functional interactions are possible with glucocorticoids and mineralocorticoids, androgens and potassium-depleting diuretics. Vigilance is required for a possible effect on the solubility of medicines eliminated with the urine (e.g. ciprofloxacin).

PREGNANCY, LACTATION and FERTILITY: No experience in pregnancy and breast-feeding. In principle, there are no objections to the use of sodium hydrogen carbonate in the appropriate

indication. Oral sodium hydrogen carbonate is well absorbed and readily crosses the placental barrier. Existing blood pressure dysregulation, such as the physiological respiratory alkalosis associated with pregnancy, may be increased due to the sodium load. No data are available on the effect on fertility.

UNDESIRABLE EFFECTS: Very rare (<1/10,000): allergic reactions due to soya oil. Incidence not known: flatulence, abdominal pain, promotion of calcium or magnesium phosphate nephrolithiasis in chronic use, hypocalcaemic tetany (muscle hyperexcitability due to decreased calcium) if dose is exceeded, exacerbation of pre-existing disorders of gastro-intestinal tract (e.g. diarrhoea).

PHARMACEUTICAL PRECAUTIONS: Store below 25°C in original pack.

LEGAL CATEGORY: POM

MARKETING AUTHORISATION NUMBER, PACK SIZE and BASIC PRICE:

PL 11243/0045. 100 capsules - £18.75

MARKETING AUTHORISATION HOLDER:

MEDICE Arzneimittel Pütter GmbH & Co. KG,
Kuhloweg 37, 58638 Iserlohn, Germany.

Marketed in the UK by MEDICE UK Ltd. Ground Floor, Unit B, The Chase, Foxholes Business Park, Hertford, Herts, SG13 7NN. Tel: 020 4582 2845 Email: medicalinformation@medice.co.uk

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