Document control

Version	Revision	Upload date	Notes
1	0	26/11/2024	

NOTHING BELOW THIS LINE

NHS
Cheshire and Merseyside

Nephrotrans® (sodium bicarbonate) for metabolic acidosis in patients with chronic renal impairment

AMBER RETAINED - Specialist initiation and stabilisation with occasional input to support non-specialist prescribing.

Recommendations

The Cheshire and Merseyside Area Prescribing Group recommend Nephrotrans® 500mg gastro-resistant capsules as an option for metabolic acidosis in patients with chronic renal impairment who do not tolerate the gastrointestinal adverse effects of standard sodium bicarbonate products.

Prescribing information

3-5g daily in divided doses, adjusted according to response. The daily dose can be achieved by taking 6 to 10 capsules of Nephrotrans® 500 mg.

Patient factors

See SmPC for information about the use of Nephrotrans® in pregnancy and breastfeeding.

Implementation notes

Patients who require oral sodium bicarbonate will already be under the care of a specialist renal service. If patients do not tolerate standard sodium bicarbonate, then the dose frequency should be adjusted e.g. from twice a day to four times a day. If patients do not tolerate the gastrointestinal adverse effects of standard sodium bicarbonate products despite adjustment of the dose frequency, then the specialist will initiate Nephrotrans® and prescribe a 1-month supply. The specialist will review the patient within 1 month of initiation. If at that review Nephrotrans® is determined to be effective and well tolerated they will write to the patient's GP to ask that they continue to prescribe. Ongoing monitoring will be undertaken by the specialist team. Patient renal function, compliance with and response to Nephrotrans® will be assessed within the hospital renal outpatient clinic. GPs will be informed if dose modification is required.

Safety

See SmPC for complete safety information including adverse effects.

Nephrotrans® is contraindicated in patients with hypersensitivity to the active substance or any of the excipients (see SmPC for details). Nephrotrans® is contraindicated in patients with hypersensitivity to soya or peanuts and in patients with metabolic alkalosis, hypokalaemia, hypernatraemia, low sodium diet or rare hereditary problems of fructose intolerance.

Cost

Nephrotrans® 500mg capsules - £18.75 (100 capsule pack) – at a dose of 5g daily the cost of 365 days treatment is £684.38 excluding VAT (source DM+D accessed 22.10.2024).

Fewer than 100 patients identified in secondary care across the Cheshire & Mersey region. Cost of standard sodium bicarbonate 500mg capsules - £3.28 (56 capsule pack) – at a dose of 5g daily the cost of 365 days treatment is £213.79 excluding VAT (source DM+D accessed 22.10.2024).

ICB approval date: 21 Nov 2024 Version 1.0
Review Nov 2026 or earlier if there is significant new evidence relating to this recommendation

Related guidance

Chronic kidney disease: assessment and management NICE guideline [NG203] Last updated: 24 November 2021. Available at: https://www.nice.org.uk/guidance/ng203

Effectiveness

Nephrotrans® 500 mg gastro-resistant capsules are dissolvable in the small intestine, thereby avoiding gastric meteorism caused by the formation of carbon dioxide gas in the acidic environment of the stomach.

20 haemodialysis patients with metabolic acidosis were treated with Nephrotrans® for 6 weeks. Patients were given 6-9 capsules daily (3-4.5g sodium bicarbonate). Before treatment there was a 2-week minimum period when no antiacidotic treatment was given. Nephrotrans® was effective in raising mean serum bicarbonate levels by 6.5 mmol/L ($p<0.005$) over a 6-week period from 16.6mmol/L to 23.1mmol/L. There was no significant increase in blood pressure or serum sodium levels during the study period. (2)

47 CKD patients (stage 3 or 4) with serum bicarbonate <21mmol/L were randomised to achieve a serum bicarbonate target of 24+/-1mmol/L or 20+/-1mmol/L. Study medication was sodium bicarbonate gastro-resistant capsules. The effects of treatment on arterial blood pressure (BP) and serum bicarbonate were reported after 8 weeks. The primary outcome was change in arterial BP at week 8 compared to baseline. In 43 randomized subjects neither systolic nor diastolic BP was affected by study group allocation. Serum bicarbonate on average increased in the high target group by 3.9 (95%CI: 3.04, 4.71) mmol/L and by 1.5 (95%CI: 0.47, 2.56) mmol/L in the low target group. (3)

References

1. Stanningly Pharma Limited. Summary of Product Characteristics for Nephrotrans® 500mg gastro-resistant capsules. Last updated 14.10.2020. Available at: https://www.medicines.org.uk/emc/product/12715/smpc Accessed: 03.07.2024
2. Stanningley Pharma (2022) Nephrotrans® Formulary Pack.
3. Gaggl M et al. Effect of oral sodium bicarbonate on 24-hour ambulatory blood pressure measurements in patients with chronic kidney disease and metabolic acidosis. Frontiers in Medicine. 2021. 8 Article 711034.

Patients who are not eligible for treatment under this policy may still be considered for treatment on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy. Follow the locally defined process.