

SUMMARY

sodium bicarbonate

BICAFRES 1000 mg,

gastro-resistant tablet

First assessment

Original French opinion adopted by the Transparency Committee on
18 January 2023

The legally binding text is the original French opinion version

Key points

Favourable opinion for reimbursement in the treatment of metabolic acidosis in adults and adolescents aged 14 years and older with chronic renal failure.

What therapeutic improvement?

No clinical added value in the therapeutic strategy.

Role in the care pathway?

CKD is the most common cause of chronic metabolic acidosis. Metabolic acidosis is defined as a plasma bicarbonate level of below 23 mmol/l. Metabolic acidosis has major clinical consequences if left untreated, and can accelerate the progression of kidney disease, bone disease and, above all, cardiac problems related, among other things, to the risk of hyperkalaemia.

The treatment of metabolic acidosis in chronic kidney disease schedules:

- an alkalinising diet (KDOQI 2020);
- in the absence of sodium overload: 3 to 6 g of sodium bicarbonates per day;
- investigation for and correction of hyperkalaemia (bicarbonates in the form of Vichy water or sodium bicarbonates can correct both disorders);
- in the event of severe acute acidosis (pH < 7.20 and bicarbonate < 10 mmol/l): emergency hospitalisation for IV infusion of sodium bicarbonates or renal dialysis.

Role of the medicinal product

BICAFRES (sodium bicarbonate) is a first-line medicinal product in the treatment of metabolic acidosis in patients with CKD.

Committee's conclusions

Clinical Benefit

- Metabolic acidosis is a serious complication of chronic kidney diseases, which can be life-threatening due to exacerbation of progression of the kidney disease.
- The medicinal product BICAFRES (sodium bicarbonate) is a curative medicinal product.
- The efficacy/adverse effect ratio of BICAFRES (sodium bicarbonate) is substantial.
- There is a therapeutic alternative, which is a pharmacy-compounded preparation.
- BICAFRES (sodium bicarbonate) is a first-line treatment for metabolic acidosis in adults and adolescents aged 14 years and older with chronic renal failure.

→ Public health benefit

Considering:

- the seriousness of the disease and its prevalence and incidence,
- the partially met medical need,
- the partial response to the identified need, with the absence of any demonstrated additional impact on morbidity and mortality or on quality of life in the absence of any available clinical studies with a robust methodology, on the organisation of care and on the care and life pathway in the absence of any data provided,

BICAFRES (sodium bicarbonate) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of BICAFRES (sodium bicarbonate) is substantial in the MA indication.

The Committee issues a favourable opinion for inclusion in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the MA indication and at the MA dosages.

Recommended reimbursement rate: 65%

Clinical Added Value

Considering:

- the available data based on an analysis of the literature demonstrating experience in the use of sodium bicarbonate in metabolic acidosis in chronic kidney disease,
- the absence of any robust clinical studies conducted with BICAFRES (sodium bicarbonate) in patients aged 14 years and older with metabolic acidosis in the context of chronic kidney disease,

- the medical need to have access to a medicinal product indicated in the treatment of metabolic acidosis in the context of chronic renal failure,

the Transparency Committee deems that BICAFRES (sodium bicarbonate) provides no clinical added value (CAV V) in the care pathway for metabolic acidosis in the context of chronic renal failure.