

SUMMARY

sodium bicarbonate

**SODIUM BICARBONATE
1.4% RENAUDIN**

solution for injection

Inclusion on list: First listing

Range supplement

**Original French opinion adopted by the Transparency Committee on
17 July 2024****The legally binding text is the original French opinion version****Summary of opinion**

Favourable opinion for reimbursement in the correction of metabolic acidosis.
No clinical added value of the new form compared to the forms already available.

Transparency Committee's conclusions**Clinical Benefit**

- ➔ In its severe forms, metabolic acidosis can be life-threatening, particularly when it is associated with moderate to severe acute renal failure.
- ➔ The proprietary medicinal product SODIUM BICARBONATE 1.4% RENAUDIN solution for injection (pack containing ten 10-ml vials) is a curative medicinal product.
- ➔ The efficacy/adverse effects ratio is high.
- ➔ There are therapeutic alternatives.

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- ➔ This product is a first-line treatment for metabolic acidosis only in certain emergency clinical situations requiring administration by injection. Due to its lower concentration and its isotonic nature, the 1.4% solution has a more limited place in the correction of severe metabolic acidosis compared to more concentrated and hypertonic solutions (4.2% and 8.4%).

➔ **Public health benefit**

SODIUM BICARBONATE 1.4% RENAUDIN solution for injection, packaged in packs of ten 10-ml vials is unlikely to have an additional impact on public health compared to the forms already listed.

The Committee deems that the clinical benefit of the proprietary medicinal product SODIUM BICARBONATE 1.4% RENAUDIN solution injectable, packaged in packs of ten 10-ml vials is substantial in the MA indication.

The Committee issues a favourable opinion for inclusion in the list of covered drugs for in-patients approved for use in the MA indication and at the MA dosages.

Clinical Added Value

This medicinal product is a range supplement that does not provide any clinical added value (CAV V) compared to the forms already listed.