

SUMMARY

povidone-iodine, isopropyl alcohol

**PERPRUP 7.25 mg/ml +
633 mg/ml**

solution for cutaneous application

First listing

Adopted by the Transparency Committee on 15 January 2025

Summary of opinion

Favourable opinion for reimbursement in the following indication: “This medicinal product should be used for the disinfection of healthy skin prior to invasive medical procedures (including surgery) and has a bactericidal and levuricidal activity.

PERPRUP is indicated in adults, adolescents and children aged 1 year or older.”

Transparency Committee’s conclusions**Clinical Benefit**

- ➔ The development of a care-related infection can impact the functional performance of patients or even be life-threatening.
- ➔ This is a preventive medicinal product.
- ➔ The efficacy/adverse effects ratio is high.
- ➔ This is a first-line treatment for the disinfection of healthy skin prior to invasive medical procedures in the same way as other antiseptic alcohol solutions.

➔ Public health benefit

Considering:

- the incidence of postoperative infections and the mortality related to these infections,
- the partially met medical need,
- the lack of evidence of an additional impact on morbidity and mortality or quality of life,
- the lack of evidence of an additional impact of the organisation of care or on the patient’s care and/or life pathway,

PERPRUP (povidone-iodine + isopropyl alcohol) is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of PERPRUP (povidone-iodine, isopropyl alcohol) 7.25 mg/ml + 633 mg/ml solution for cutaneous application is substantial in the MA indication.

The Committee issues a favourable opinion for inclusion of PERPRUP (povidone-iodine, isopropyl alcohol) 7.25 mg/ml + 633 mg/ml solution for cutaneous application in the list of covered drugs for inpatients approved for use.

Clinical Added Value

Considering:

- the medical need partially met by alcohol solutions containing povidone-iodine and chlorhexidine given the care-related infections that occur despite the use of these antiseptic solutions,
- data relative to the PREVAIL-FX proprietary medicinal product, solution containing 8.3% povidone-iodine and 72.5% isopropyl alcohol (antiseptic solution with the same composition as PERPRUP but non-sterile) contained in an applicator device similar to that of PERPRUP, derived from the SUR-19IPVPV01 prospective study conducted on healthy skin prior to an invasive medical procedure, demonstrating a reduction in the number of cutaneous micro-organisms on the abdomen and the groin compared to the baseline value higher than the expected activity standards, 10 minutes and 6 hours after application to the skin,

but:

- the lack of evidence of the efficacy of PERPRUP on a relevant clinical endpoint, such as reduction of the incidence of postoperative site infections,
- the lack of robust comparative data versus the available alternatives France,

the Committee deems that PERPRUP (iodine povidone, isopropyl alcohol) 7.25 mg/ml + 633 mg/ml solution for cutaneous application provides no clinical added value (CAV V) compared to the other available antiseptic alcohol solutions containing povidone-iodine.