



TRANSPARENCY COMMITTEE SUMMARY 17 NOVEMBER 2021

The legally binding text is the original French opinion version

***retinol (vitamin A), cholecalciferol (vitamin D3), all-rac- α -tocopherol (vitamin E),
phytomenadione (vitamin K1), ascorbic acid (vitamin C), thiamine (vitamin B1),
riboflavin (vitamin B2), pyridoxine (vitamin B6), cyanocobalamin (vitamin B12),
folic acid (vitamin B9), pantothenic acid (vitamin B5), biotin (vitamin B7),
nicotinamide (vitamin B3)
VIANT, powder for solution for infusion***

First assessment

► Key points

Favourable opinion for reimbursement for parental vitamin replacement when oral or enteral nutrition is impossible, insufficient or contraindicated, VIANT being indicated in adults and children aged 11 years and older.

► What therapeutic improvement?

No clinical added value in the therapeutic strategy.

► Role in the care pathway?

Apart from the supply of proteins and energy in the form of carbohydrates and fats, parenteral nutrition requires the supply of trace elements, electrolytes and vitamins. Vitamins are an essential component of nutrition. They help maintain the body's integrity and normal functions. The parenteral administration of vitamins prevents the clinical sequelae of vitamin deficiencies when foods cannot or must not be taken orally.

Three multivitamin complex products are currently available in France: CERNEVIT, VITALIPIDE and SOLUVIT (see Annex for the composition of the three proprietary medicinal products). To supply fat-soluble and water-soluble vitamins, it is possible to use either CERNEVIT, which contains water-soluble and fat-soluble vitamins and no vitamin K1, or to combine VITALIPIDE ADULT (fat-soluble vitamins) and SOLUVIT (water-soluble vitamins).

Role of the medicinal product in the care pathway

VIANT represents an alternative to the proprietary medicinal products already available in France to supply vitamins in the context of parenteral nutrition in adults and children aged 11 years and older.

COMMITTEE'S CONCLUSIONS

Considering all of this information and further to debate and voting, the Committee considers:

Clinical benefit

- ▶ Situations requiring parenteral nutrition (under-nutrition) are generally serious.
- ▶ The proprietary medicinal product VIANT can be used to correct or prevent a vitamin deficiency associated with under-nutrition.
- ▶ Its efficacy/adverse effects ratio is high.
- ▶ There are therapeutic alternatives (other vitamin solutions).
- ▶ This is a first-line treatment.

Public health impact

Considering:

- the essential nature of vitamin supplementation for the treatment or prevention of under-nutrition;
- the currently met medical need,
- the lack of additional response to the already met need,

VIANT is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of VIANT, powder for solution for infusion 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 marketing authorisation indication and dosages.

- ▶ **Recommended reimbursement rate: 65%.**

Clinical Added Value

Considering:

- the medical need already met by the existence of alternatives, but considering the need to have access to additional alternatives due, in particular, to supply tensions and potential stock shortages,
- the established medical use of parenteral nutrition in certain patients, when oral or enteral nutrition is impossible, insufficient or contraindicated,

But taking into account:

- the absence of any available specific clinical data for the proprietary medicinal product VIANT, powder for solution for infusion,

the Transparency Committee considers that VIANT powder for solution for infusion provides no clinical added value (CAV V) for parental vitamin replacement in adults and children aged 11 years and older.