

Original French opinion adopted by the Transparency Committee

The legally binding text is the original French opinion version

SUMMARY

thiotepa

TEPADINA 200 mg

powder for concentrate for solution for infusion

Inclusion on list: First listing

Range supplement

Adopted by the Transparency Committee on 26 February 2025

Summary of opinion

Favourable opinion for reimbursement in combination with other chemotherapy medicinal products:

- with or without total body irradiation (TBI), as conditioning treatment prior to allogeneic or autologous haematopoietic stem cell transplantation (HSCT) in haematological diseases in adult and paediatric patients;
- when high dose chemotherapy with HSCT support is appropriate for the treatment of solid tumours in adult and paediatric patients.

No clinical added value of the new form compared to the forms already listed.

Transparency Committee's Conclusions

Clinical Benefit

- ➔ Diseases requiring conventional haematopoietic stem cell transplantation are life-threatening.
- ➔ The proprietary medicinal product TEPADINA (thiotepa) is a conditioning treatment prior to haematopoietic stem cell transplantation (HSCT)
- ➔ The efficacy/adverse effects ratio of TEPADINA (thiotepa), in combination with other chemotherapies, is high.
- ➔ This is a first-line treatment in view of the therapies available.

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→ Public health benefit

TEPADINA (thiotepa) is unlikely to have an additional impact on public health compared to the forms already listed.

The Committee considers that the clinical benefit of TEPADINA (thiotepa) is substantial in the MA indication.

The Committee issues a favourable opinion for inclusion in the list of covered drugs for inpatients 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.