

SUMMARY

normal human immunoglobulin

GAMUNEX 100 mg/mL,

solution for intravenous injection

Inclusion on list: Indication extension

Original French opinion adopted by the Transparency Committee on
19 July 2023

The legally binding text is the original French opinion version

Transparency Committee's conclusions**Clinical Benefit**

- Measles is a contagious disease that can have serious complications.
- This is a preventive medicinal product.
- The efficacy/adverse effects ratio is high.
- This is a first-line treatment in the event of contraindication to active immunisation.

→ Public health benefit

GAMUNEX (normal human immunoglobulin) is unlikely to have an additional impact on public health.

The Committee considers that the clinical benefit of GAMUNEX (normal human immunoglobulin) is high in measles pre-/post exposure prophylaxis for susceptible adults, children and adolescents (0-18 years) in whom active immunisation is contraindicated or not advised. The Committee issues a favourable opinion for inclusion in the hospital formulary list of reimbursed proprietary medicinal products approved for use in the MA indication and dosages.

Clinical Added Value

GAMUNEX (normal human immunoglobulin) provides no clinical added value (CAV V) in measles pre-/post exposure prophylaxis for susceptible adults, children and adolescents (0-18 years) in whom active immunisation is contraindicated or not advised.