



TRANSPARENCY COMMITTEE SUMMARY 14 SEPTEMBER 2022

The legally binding text is the original French opinion version

prednisolone pivalate
ULTARCORLENE 5 mg/g, eye ointment

First assessment

Key points

Approval of reimbursement for allergy-induced severe inflammatory conditions, and non-infectious severe inflammatory conditions of the ocular surface and the anterior segment of the eye.

Therapeutic improvement?

No therapeutic improvement.

Role in therapeutic strategy?

Treatments of allergy-induced severe inflammatory conditions, and non-infectious severe inflammatory conditions of the ocular surface and the anterior segment of the eye generally use local corticosteroids, but depending on the cause, they may be associated with lifestyle and dietary or environmental measures, adjunctive therapies (based on medicinal products or not) or other local anti-inflammatory treatments (NSAID, ciclosporin) or, in the context of underlying autoimmune diseases, systemic corticosteroid or immunosuppressant treatments.

Role of the medicinal product

ULTARCORLENE 5 mg/g (prednisolone pivalate), eye ointment, is a first-line topical anti-inflammatory eye treatment for allergy-induced severe inflammatory conditions, and non-infectious severe inflammatory conditions of the ocular surface and the anterior segment of the eye.

COMMITTEE'S CONCLUSIONS

Clinical Benefit

- ▶ Conjunctival conditions of allergic or inflammatory origin induce eye signs and symptoms which are not severe, but may impair quality of life. They can cause severe complications with potential eye-threatening consequences.
- ▶ The proprietary medicinal product ULTARCORLENE 5 mg/g (prednisolone pivalate), eye ointment, is a curative and preventive medicinal product.
- ▶ The efficacy/adverse effect ratio is significant.
- ▶ This proprietary medicinal product is a first-line topical anti-inflammatory eye treatment for allergy-induced severe inflammatory conditions, and non-infectious severe inflammatory conditions of the ocular surface and the anterior segment of the eye (see Therapeutic Strategy section).
- ▶ Alternative medications are available.

Public health benefit

Considering:

- the severity of severe inflammatory conditions of the ocular surface of allergic and non-infectious origin, given that they substantially impair patients' quality of life and may cause loss of visual acuity,
- the many aetiological causes, some of which may be common, such as eye allergy, and the management of inflammatory complications post-eye surgery (in particular cataract surgery),
- the identified partially met medical need and the benefit of having a topical corticosteroid monotherapy in preservative-free eye ointment form,

- the lack of specific data with the active substance of ULTARCORLENE (prednisolone pivalate) and with the same formulation (eye ointment), but the evidence of the efficacy of prednisolone acetate in eye drop and gel form, and the significant follow-up in terms of use of this medicinal product internationally,
- the lack of evidence of an impact in terms of the patient's quality of life and care or life pathway, ULTARCORLENE (prednisolone) is not likely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the actual clinical benefit of ULTARCORLENE 5 mg/g (prednisolone pivalate), eye ointment is significant in the marketing authorisation indication.

► **Recommended reimbursement rate: 65%**

The Committee approves inclusion in the list of proprietary medicinal products qualifying for reimbursement under social security and in the list of proprietary products approved for community use for the indication and at the dosages of the marketing authorisation.

Clinical Added Value

Considering:

- the partially met medical need particularly in terms of ocular corticosteroid monotherapy, in particular in preservative-free eye ointment form,

But:

- the literature data furnished which did not provide evidence of the superiority of 1% prednisolone eye drops over dexamethasone or fluorocortolone eye drops in robust studies,
- the lack of studies demonstrating the superiority of 0.5% prednisolone eye ointment over other ophthalmic corticosteroids,

the Committee deems that the proprietary medicinal product ULTARCORLENE 5 mg/g (prednisolone pivalate), eye ointment, provides no clinical added value (CAV) in the management of allergy-induced severe inflammatory conditions, and non-infectious severe inflammatory conditions of the ocular surface and the anterior segment of the eye.