HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE

SUMMARY

17 FEBRUARY 2021

The legally binding text is the original French opinion version

dexamethasone, tobramycin

TOBRADEX eye drops, suspension

Reevaluation

Key points

◗ Maintenance of the favourable opinion for reimbursement in the local anti-inflammatory and antibacterial treatment of the eye in adults and children over the age of 2 years, following eye surgery.

◗ Maintenance of the favourable opinion for reimbursement in the local anti-inflammatory and antibacterial treatment of the eye in adults and children over the age of 2 years of infections with an inflammatory component due to tobramycin-susceptible microorganisms, excluding infectious conjunctivitis.
Unfavourable opinion for reimbursement in other situations, including infectious conjunctivitis.

Role in the care pathway

Eye surgery:

Given the available data and the validated care pathway, a fixed-combination ophthalmic corticosteroid + antibiotic treatment may be useful in the first-line treatment of inflammatory eye reactions following surgery and with the aim of preventing postoperative infectious complications in the eye. However, since the treatment durations differ for corticosteroids (treatment for several weeks with reduction of doses after 2 weeks of treatment) and antibiotics (until closure of incisions, i.e. 8 to 10 days maximum) and due to the risk of antibiotic resistance, these combinations are only useful for the antibiotic treatment period, i.e. 8 to 10 days maximum.

Role of the proprietary medicinal product in the care pathway:

TOBRADEX (dexamethasone, tobramycin) is a first-line treatment in the early management of infectious and inflammatory complications of the eye following eye surgery. Although the risk of antibiotic resistance is low with antibiotic eye drops, the correct use of antibiotics requires that their use be restricted. Consequently, their prescription must be limited to the antibiotic treatment duration (i.e. 8 to 10 days, until closure of incisions).

Eye infections:

In the context of the anti-inflammatory and antibacterial treatment of the eye during eye infections with an inflammatory component, the data supplied for these combinations does not support the benefit of using corticosteroid + antibiotic(s) ophthalmic products in these conditions. However, according to expert opinion, the combination of a topical corticosteroid with a topical antibiotic could be of benefit in rare situations in the event of a severe inflammatory reaction in case of blepharitis, a chalazion, a stye or a corneal abscess.

More specifically, in the event of a corneal abscess, a corticosteroid + antibiotic(s) combination may be administered once the infection has been controlled (for a very short period). In the event of a stye, this type of combination should be reserved for highly inflammatory recurrent forms.

Infectious conjunctivitis is generally viral and benign, resolving spontaneously with eye-washes. Antibiotic treatment is reserved for severe forms of infectious conjunctivitis and combination with a corticosteroid is not justified.

Role in the therapeutic strategy:

TOBRADEX (dexamethasone, tobramycin) is a second-line treatment in the local anti-inflammatory and antibacterial treatment of the eye, of eye infections with an inflammatory component due to tobramycin-susceptible microorganisms, excluding infectious conjunctivitis. Its prescription must be reserved for highly inflammatory forms and limited to the antibiotic treatment duration (i.e. 8 days maximum).

In other situations, including infectious conjunctivitis, this proprietary medicinal product has no role in the care pathway.

COMMITTEE'S CONCLUSIONS

Clinical benefit

Eye surgery

◗ Eye infections and inflammatory reactions complicating eye surgery, can be sight-threatening.

◗ TOBRADEX (dexamethasone, tobramycin) combining a corticosteroid and an antibiotic is a curative and preventive anti-inflammatory and antibiotic treatment.

◗ The dexamethasone + tobramycin combination has demonstrated its superiority compared to tobramycin alone to reduce eye inflammation in the context of cataract surgery. The efficacy/adverse effects ratio of this proprietary medicinal product is moderate.

◗ Given the current care pathway, this proprietary medicinal product is a first-line treatment in the management of infectious and inflammatory complications of the eye following eye surgery. Treatment must not exceed 8 to 10 days, until healing of the incisions.

◗ There are therapeutic alternatives.

◗ Public health impact:

Considering:

- the serious consequences on the visual prognosis of infectious and inflammatory complications following eye surgery,
- the medical need met by other ophthalmic products enabling the combination of a corticosteroid and antibiotic in the form of a fixed or free active substance combination,
- the absence of data enabling demonstration of an impact in terms of morbidity or quality of life,
- the lack of evidence to support the absence of a deterioration in the care and life pathway,
- the absence of any demonstrated impact on the organisation of care,

TOBRADEX (dexamethasone, tobramycin) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of TOBRADEX (dexamethasone, tobramycin) remains moderate in the local anti-inflammatory and antibacterial treatment of the eye in adults and children over the age of 2 years following eye surgery.

The Committee issues a favourable opinion for maintenance of inclusion in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the local anti-inflammatory and antibacterial treatment of the eye in adults and children over the age of 2 years following eye surgery.

Eye infections with an inflammatory component

◗ Eye infections are generally benign but can worsen or become painful due to the associated inflammatory reaction.

◗ TOBRADEX (dexamethasone, tobramycin) combining a corticosteroid and an antibiotic is a curative anti-inflammatory and antibiotic treatment.

◗ The efficacy/adverse effects ratio of this medicinal product has not been adequately established in this indication.

◗ This proprietary medicinal product is a second-line treatment in the local anti-inflammatory and antibacterial treatment of the eye, of eye infections with an inflammatory component due to tobramycin-susceptible microorganisms, excluding infectious conjunctivitis. Its prescription must be reserved for highly inflammatory forms and limited to the antibiotic treatment duration (i.e. 8 days maximum).
In other situations, including infectious conjunctivitis, this proprietary medicinal product has no role in the care pathway.

◗ There are therapeutic alternatives.

◗ Public health impact:
Considering:
- the generally benign nature of eye infections, with the prescription of a topical antibiotic only being justified in the event of severe complications,
- the medical need met by medicinal products as monotherapy,
- the absence of data enabling demonstration of an impact in terms of morbidity or quality of life,
- the absence of any demonstrated impact on the organisation of care,

TOBRADEX (dexamethasone, tobramycin) is unlikely to have an additional impact on public health.

Considering these elements, the Committee deems that, in the local anti-inflammatory and antibacterial treatment of the eye in adults and children over the age of 2 years, the clinical benefit of TOBRADEX (dexamethasone, tobramycin) becomes:

- **low in eye infections with an inflammatory component, excluding infectious conjunctivitis,**
- **insufficient to justify public funding cover in view of the available alternatives in other situations, including infectious conjunctivitis.**

The Committee issues a favourable opinion for maintenance of inclusion in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the local anti-inflammatory and antibacterial treatment of the eye in adults and children over the age of 2 years, of eye infections with an inflammatory component, excluding infectious conjunctivitis.

The Committee issues an unfavourable opinion for reimbursement in other situations, including infectious conjunctivitis.