HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
OPINION
05 FEBRUARY 2020

triamcinolone acetonide
NASACORT 55 µg per dose, nasal spray, suspension

New indications

Key points

Favourable opinion for reimbursement in the indication extension for the treatment of symptoms of:

- seasonal allergic rhinitis in children aged 2 to 5 years
- perennial allergic rhinitis in children and adolescents aged 2 to 17 years.

What therapeutic improvement?

No clinical added value.

Role in the care pathway?

In case of allergy, the first measure to be implemented is avoidance of the allergen as far as possible, which can be difficult in the event of allergy to pollens. In children and adolescents, as in adults, the medicinal treatment of allergic rhinitis first involves oral or nasal antihistamines and cromones, then nasal corticosteroids.

In the 2016 ARIA recommendations, inhaled corticosteroid + oral or intranasal antihistamine combinations are proposed in patients with moderate to severe forms. However, the level of evidence for these recommendations is low. If these treatments fail, a short course of oral corticosteroids may

be prescribed. In severe rhinitis not responding to corticosteroid therapy, allergen immunotherapy may be envisaged.

Role of the medicinal product in the care pathway:

NASACORT is an option following the failure of anti-H1 antihistamines in non-severe allergic rhinitis. It may be prescribed from the onset in the event of severe allergic rhinitis.

The lowest effective dose of nasal corticosteroids must be sought.

COMMITTEE'S CONCLUSIONS

Clinical Benefit

◗ Season and perennial allergic rhinitis are benign conditions. However, the symptoms can impair quality of life, particularly in severe forms.

◗ NASACORT 55 µg/ml (triamcinolone acetonide), nasal spray, suspension is a symptomatic treatment.

◗ In view of its low effect size in terms of reducing allergic rhinitis symptoms and its safety profile involving numerous systemic risks, in particular the risk of a growth retardation, as observed in a paediatric study, its efficacy/adverse effects ratio is low in the indication extension for the treatment of symptoms of seasonal allergic rhinitis in children aged 2 to 5 years and perennial allergic rhinitis in children and adolescents aged 2 to 17 years.

◗ NASACORT is an option following the failure of anti-H1 antihistamines in non-severe allergic rhinitis. It may be prescribed from the onset in the event of severe allergic rhinitis. The lowest effective dose must be sought.

◗ There are therapeutic alternatives.

Public health impact:
Considering:
- the absence of seriousness of the disease but the resulting impairment in quality of life in severe forms,
- the high frequency of allergic rhinitis, particularly in children,
- the identified partially met medical need,
- the low effect size in terms of reducing allergic rhinitis symptoms in view of its safety profile involving numerous systemic risks, in particular the risk of growth retardation in children, as observed in a study, and the absence of any demonstrated impact in terms of quality of life,
- the absence of an additional impact on the organisation of care,
- the lack of additional response to the identified need,

NASACORT (triamcinolone acetonide) is unlikely to have an additional impact on public health compared to other nasal corticosteroid medicines.

Considering these elements, the Committee deems that the clinical benefit of NASACORT 55 µg per dose (triamcinolone acetonide), nasal spray, suspension is low in the indication extension to the treatment of symptoms of:
- **seasonal allergic rhinitis in children aged 2 to 5 years**
- **perennial allergic rhinitis in children and adolescents aged 2 to 17 years.**

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 indication extension to the treatment of symptoms of:
- **seasonal allergic rhinitis in children aged 2 to 5 years**
- **perennial allergic rhinitis in children and adolescents aged 2 to 17 years**

and at the MA dosages.

Clinical Added Value

Considering:
- **the demonstration of the superiority of triamcinolone acetonide compared to placebo in only one of the two studies conducted and only one of the two co-primary endpoints studied (nasal score assessing nasal congestion, rhinorrhoea and sneezing), in paediatric patients with perennial allergic rhinitis,**

- **the low size effect observed on reduction of the nasal score compared to placebo,**
- **the absence of data in seasonal allergic rhinitis,**
- **the absence of data in children aged over 12 years in perennial allergic rhinitis,**
- **the absence of quality of life data,**
- **the risks in terms of growth retardation in children and adverse effects related to systemic absorption in the event of prolonged treatment,**
- **the absence of comparison with the other nasal corticosteroids available,**

NASACORT 55 µg/ml (triamcinolone acetonide), nasal spray, suspension provides no clinical added value (CAV V) in the care pathway for the treatment of symptoms of seasonal allergic rhinitis in children aged 2 to 5 years and perennial allergic rhinitis in children and adolescents aged 2 to 17 years.