HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
SUMMARY
1 DECEMBER 2021

The legally binding text is the original French opinion version

Influenza vaccine, surface antigen, inactivated
INFLUVAC TETRA, suspension for injection in pre-filled syringe

New indication

Key points

Favourable opinion for reimbursement in the prevention of influenza in children from 6 months of age.

What therapeutic improvement?

No clinical added value in the therapeutic strategy.

Role in the care pathway?

In France, vaccination against seasonal influenza is recommended in all people aged 65 years and over and in the following special populations (see vaccine schedule):

- pregnant women, regardless of the trimester of pregnancy;

- people, from 6 months of age, with conditions promoting the onset of serious influenza complications;

- obese people;

- people staying in follow-on care facilities and medical-social care home residents;

- **families of infants under 6 months of age with serious influenza risk factors**, as well as the families of immunocompromised individuals;

- professionals in regular and prolonged contact with individuals with a severe influenza risk, in particular healthcare professionals and flight crews.

According to the vaccine recommendation adopted by the HAS board on 21 October 2021 relative to the INFLUVAC TETRA vaccine: “The HAS considers that the INFLUVAC TETRA vaccine may be used in accordance with its MA for infants and children aged from 6 to 35 months and in the context of the French seasonal influenza vaccination strategy aimed at preventing serious forms and deaths thanks to vaccination of specific populations”.

Role of the medicinal product in the care pathway

The Committee considers that INFLUVAC TETRA influenza vaccine (surface antigen, inactivated) may be used in accordance with its MA in children from 6 months of age for whom influenza vaccination is recommended, with the aim of preventing serious forms and deaths related to seasonal influenza (see current vaccine schedule).

COMMITTEE'S CONCLUSIONS

Considering all of this information and further to debate and voting, the Committee considers:

Clinical benefit

◗ Influenza is a highly contagious acute viral disease. Sometimes serious complications develop more readily in subjects already weakened by underlying diseases and/or over 65 years of age.

◗ This proprietary medicinal product is a preventive treatment.

◗ The efficacy (immunogenicity)/adverse effects ratio of INFLUVAC TETRA is high.

◗ There are alternative vaccines for the prophylaxis of influenza in infants and children from 6 months of age, i.e. standard-dose quadrivalent vaccines (VAXIGRIPTETRA).

◗ INFLUVAC TETRA may be used in accordance with its MA in the context of current vaccine recommendations, aimed at preventing serious forms and seasonal influenza-related deaths.

Public health impact

As in adults and children from 3 years of age, considering:

- the frequency (2.5 million people affected each year) and potential severity of influenza, which can cause serious complications, particularly in individuals with specific risk factors (almost 3,000 serious cases admitted to intensive care units in the 2017-2018 season),
- the public health objective, aimed at reducing the morbidity and mortality of this infection,
- the fact that vaccination is the most effective tool to prevent influenza and its complications,
- the objective of improving vaccination coverage to reach a minimum of 75% in the populations targeted by vaccination,
- the medical need to expand the offer in order to be able to guarantee seasonal vaccination of all recommended populations in subsequent influenza seasons insofar as only one vaccine has an MA in the target age category (6 months - 3 years),
- the immunogenicity and safety of INFLUVAC TETRA, which are comparable to those of other inactivated quadrivalent vaccines,
- the expected impact of vaccination on the organisation of care,

INFLUVAC TETRA influenza vaccine (surface antigen, inactivated) is likely to have an additional impact on public health, in the same way as the other vaccine available in infants and children from 6 months of age to prevent influenza. However, this impact remains dependent, firstly, on achievement of an adequate vaccination coverage rate in the targeted populations and, secondly, on the protection provided by the seasonal vaccine against the viral strains circulating.

Considering all these elements, the Committee deems that the clinical benefit of INFLUVAC TETRA influenza vaccine (surface antigen, inactivated) is substantial in the prevention of influenza in infants and children from 6 months to 3 years of age for whom influenza vaccination is recommended.

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 prevention of influenza in infants and children from 6 months to 3 years of age, only in the populations recommended by the HAS in 2021 and at the MA dosages.

◗ **Recommended reimbursement rate: 65%**

Clinical Added Value

Considering:

- The immunogenicity induced by INFLUVAC TETRA influenza vaccine in children over 6 months of age,
- A protective efficacy against influenza of 54% [95% CI: 0.37 to 0.66] (circulating seasonal influenza strain) and 68% [95% CI: 0.45 to 0.81] (antigenically coherent strains) in the study population of infants and young children, and a good safety profile,

but:

- the absence of comparative clinical efficacy data for INFLUVAC TETRA compared to VAXIGRIPTETRA (quadrivalent influenza vaccine),

the Committee considers that INFLUVAC TETRA influenza vaccine provides no clinical added value (CAV V) compared to VAXIGRIPTETRA, indicated for the prevention of influenza in infants and children aged from 6 months to 3 years for whom vaccination is recommended.