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, adjuvanted)
FLUAD TETRA, suspension for injection in pre-filled syringe

First assessment

Key points

Favourable opinion for reimbursement in prophylaxis of influenza in people aged 65 years and over.

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;

- people in the environment of infants under 6 months of age with serious influenza risk factors, as well as the people in the environment 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 18 November 2021 relative to FLUAD TETRA vaccine: “At the end of its assessment, the HAS considers that FLUAD TETRA can be used, in the same way as the other influenza vaccines marketed in France, within the framework of the French vaccination strategy against seasonal influenza, the aim of which is to reduce severe forms and deaths attributable to influenza. In accordance with its marketing authorisation, FLUAD TETRA must be used in patients 65 years of age and older.”

Role of the medicinal product in the care pathway

The Committee considers that FLUAD TETRA influenza vaccine (surface antigen, inactivated, adjuvanted) is a new method for the prevention of seasonal influenza in people aged 65 years and over, in the same way as the other standard-dose or high-dose quadrivalent vaccines available.

The Committee reiterates the fact that vaccination is the most effective tool to prevent influenza and its associated complications, particularly in at-risk populations. Good vaccination coverage, including in caregivers, is essential.

In addition, protective hygiene measures (wearing surgical masks and frequent hand washing) help limit the risk of transmission and contamination, particularly in very young children and people with specific risk factors. These two measures form the cornerstone of influenza prevention.

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 most likely in subjects 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 FLUAD TETRA is high.

◗ There are alternative vaccines for the prophylaxis of influenza in adults, i.e., standard-dose and high-dose quadrivalent vaccines (INFLUVAC TETRA, VAXIGRIPTETRA and EFLUELDA).

◗ FLUAD TETRA may be used in accordance with its MA (from the age of 65 years) and, in this population, in the same way as the other standard-dose and high-dose quadrivalent influenza vaccines available, constitutes a new method for the prevention of seasonal influenza, aimed at reducing serious forms and deaths.

Public health impact

Considering:

- the frequency (2.5 million people affected each year) and potential severity of influenza, which can cause serious complications and deaths, particularly in individuals weakened by underlying diseases and/or aged 65 years and over (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,
- the immunogenicity induced by FLUAD TETRA, non-inferior to that of the adjuvanted trivalent vaccines against four influenza strains, with a better immune response to the additional strain B,
- the possible additional impact on the basis of clinical experience reported with the trivalent vaccine adjuvanted with MF-59 (FLUAD) in terms of improved immunogenicity and vaccine efficacy compared to non-adjuvanted trivalent vaccines in people aged 65 years and over, but not formally demonstrated in the absence of clinical comparative studies between FLUAD TETRA and the standard-dose quadrivalent vaccines currently available in France,
- the expected impact of vaccination on Health Care organization ,

FLUAD TETRA influenza vaccine (surface antigen, inactivated, adjuvanted) is likely to have an impact on public health, in the same way as the other vaccines available 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 FLUAD TETRA influenza vaccine (surface antigen, inactivated, adjuvanted) is substantial in the prophylaxis of influenza in people aged 65 years and over for whom influenza vaccination is recommended.

The Committee issues a favourable opinion for inclusion/maintenance in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products

approved for use in the prophylaxis of influenza in people aged 65 years and over for whom influenza vaccination is recommended and according to the posology section of the MA.

- **Recommended reimbursement rate: 65%**

Clinical Added Value

Considering, on the one hand:

- the immunogenicity induced by FLUAD TETRA influenza vaccine (surface antigen, inactivated, adjuvanted) non-inferior to that of the adjuvanted trivalent (aTIV) vaccines not marketed in France against four influenza strains, with a better immune response to the additional strain B, and a satisfactory safety profile;
- data from the literature relative to clinical experience with adjuvanted trivalent (aTIV) influenza vaccines suggesting a superior efficacy to that of non-adjuvanted trivalent vaccines but comparable to that of high-dose trivalent vaccines;

but considering, on the other hand:

- the lack of demonstration of the efficacy of FLUAD TETRA for the prevention of influenza cases (strains A and/or B) confirmed by RT-PCR in adults aged 65 years or more in the V118_18 study, and
- the absence of comparative clinical efficacy data for FLUAD TETRA versus the standard-dose or high-dose tetravalent vaccines marketed in France,

the Transparency Committee considers that FLUAD TETRA influenza vaccine (surface antigen, inactivated, adjuvanted) provides no clinical added value (**CAV V**) in the active immunisation of people aged 65 years and over for the prevention of influenza compared to the other available vaccines indicated in this population.