HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
SUMMARY
24 JUNE 2020

The legally binding text is the original French opinion version

Quadrivalent influenza vaccine (split virion, inactivated), 60 micrograms HA / strain
EFLUELDA suspension for injection in a pre-filled syringe

First assessment

Key points

Favourable opinion for reimbursement in the prevention of influenza in people aged 65 years and over[1].

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;

[1] For more information, see page 3

- 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 20/05/2020 relative to the EFLUELDA vaccine[2] (see annex), *"since this vaccine induces better protection in elderly people compared to standard-dose trivalent vaccines, EFLUELDA may be used, in the same way as other influenza vaccines, in accordance with its MA, i.e., from the age of 65 years in the context of the French seasonal influenza vaccination strategy aimed at reducing serious forms and deaths. No data are available concerning other special populations, such as immunocompromised subjects or adults under the age of 65 years at risk of severe influenza and eligible for vaccination recommendations".*

Role of EFLUELDA defined by the Transparency Committee:

The Committee considers that EFLUELDA high-dose (60 µg) quadrivalent vaccine 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 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 care-givers, 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.

[2] https://www.has-sante.fr/jcms/p_3186428/fr/place-du-vaccin-quadrivalent-haute-dose-efluelda-dans-la-strategie-de-vaccination-contre-la-grippe-saisonniere-chez-les-personnes-de-65-ans-et-plus

COMMITTEE'S CONCLUSIONS

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 immunogenicity/adverse effects ratio of EFLUELDA is high.

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

◗ EFLUELDA may be used in accordance with its MA (from the age of 65 years) and, in this population and in the same way as the other standard-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 EFLUELDA non-inferior to that of the "High Dose" trivalent vaccine marketed in the USA but not available in France (FLUZONE HD) against the three strains common to both vaccines, with a better immune response to the additional strain B,
- the possible additional impact on the basis of clinical experience reported with the "High Dose" trivalent vaccine in terms of improved immunogenicity and vaccine efficacy compared to standard-dose trivalent vaccines in people aged 65 years and over, but not formally demonstrated in the absence of comparative studies between EFLUELDA and the standard-dose quadrivalent vaccines currently available in France,
- the expected impact of vaccination on the organisation of care,

EFLUELDA 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 EFLUELDA is substantial in the prevention of influenza in people aged 65 years and over and 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 people aged 65 years and over and for whom influenza vaccination is recommended.

Clinical Added Value

Considering:

- **the immunogenicity induced by EFLUELDA ("high-dose" inactivated quadrivalent influenza vaccine) non-inferior to that of the "high dose" trivalent vaccine marketed in the USA (FLUZONE trivalent HD not available in France) against the three strains common to both vaccines, with a better immune response to the additional strain B and a satisfactory safety profile,**
- **the possible benefit of a high-dose quadrivalent vaccine compared to a standard-dose quadrivalent vaccine considering the results of studies having demonstrated a clinical superiority of the high-dose trivalent vaccine (marketed in the USA) compared to standard-dose trivalent vaccines in subjects aged 65 years, with a modest relative reduction in the incidence of virologically confirmed influenza cases (24.2% [9.7% - 36.5%]) and, to a lesser degree, hospitalisations due to influenza or respiratory or cardiovascular conditions (8% to 27%) or hospitalisations for all causes (heterogeneous results), and without a demonstrated impact on either mortality or functional decline,**

but in the absence comparative clinical efficacy data for EFLUELDA versus the standard-dose quadrivalent vaccines marketed in France,

the Committee considers that EFLUELDA ("high-dose" inactivated quadrivalent influenza vaccine) 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.