17 October 2024
EMA/CHMP/452577/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Fluad

influenza vaccine (surface antigen, inactivated, adjuvanted)

On 17 October 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Fluad, a vaccine intended for the prevention of influenza disease in people aged 50 years and older.

The applicant for this medicinal product is Seqirus Netherlands B.V.

Fluad will be available as a suspension for injection in pre-filled syringes. Fluad is an influenza vaccine (ATC code: J07BB02). It contains haemagglutinin and neuraminidase surface antigens purified from 3 inactivated strains: two A subtypes (H1N1 and H3N2) and one B type (Victoria lineage). Fluad also contains the adjuvant MF59C.1, which increases the effect of the vaccine by enhancing the immune response. Fluad provides protection against the influenza viruses it targets by inducing the production of neutralising antibodies against viral haemagglutinin.

The benefit of Fluad is its ability to induce an immune response in people aged 50 years and older, similar to that of previously authorised trivalent and quadrivalent vaccines. The most common side effects with Fluad are pain and tenderness at injection site, myalgia, headache, fatigue and arthralgia.

The full indication is:

> Prophylaxis of influenza in adults 50 years of age and older.
>
> Fluad should be used in accordance with official recommendations.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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