9 November 2023
EMA/CHMP/492465/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Fluad Tetra

influenza vaccine (surface antigen, inactivated, adjuvanted)

On 9 November 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Fluad Tetra. The marketing authorisation holder for this medicinal product is Seqirus Netherlands B.V.

The CHMP adopted a change to the existing indication to include prophylaxis of influenza in adults from 50 years of age. For information, the full indication for Fluad Tetra will therefore be as follows:[2]

> Prophylaxis of influenza in **adults** ~~the elderly (65~~ **50** years of age and older~~)~~.
>
> Fluad Tetra should be used in accordance with official recommendations.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to 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
[2] New text in bold, removed text as strikethrough

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