

| <u>MA (EU) number</u> | <u>(Invented) name</u> | <u>Strength</u> | <u>Pharmaceutical Form</u> | <u>Route of Administration</u> | <u>Immediate Packaging</u>                | <u>Content (concentration)</u> | <u>Pack size</u>       |
|-----------------------|------------------------|-----------------|----------------------------|--------------------------------|---|--------------------------------|------------------------|
| EU/1/20/1433/001      | Fluad Tetra            | --1             | Suspension for injection   | Intramuscular use              | pre-filled syringe (glass) with needle    | 0.5 ml                         | 1 pre-filled syringe   |
| EU/1/20/1433/002      | Fluad Tetra            | --1             | Suspension for injection   | Intramuscular use              | pre-filled syringe (glass) without needle | 0.5 ml                         | 1 pre-filled syringe   |
| EU/1/20/1433/003      | Fluad Tetra            | --1             | Suspension for injection   | Intramuscular use              | pre-filled syringe (glass) with needle    | 0.5 ml                         | 10 pre-filled syringes |
| EU/1/20/1433/004      | Fluad Tetra            | --1             | Suspension for injection   | Intramuscular use              | pre-filled syringe (glass) without needle | 0.5 ml                         | 10 pre-filled syringes |

--1 Each 0.5 ml dose contains:

Influenza virus surface antigens (haemagglutinin and neuraminidase), inactivated, of the following strains\*:

A/Victoria/2570/2019 (H1N1)pdm09 - like strain (A/Victoria/2570/2019 IVR-215)

15 µg HA\*\*

A/Darwin/9/2021 (H3N2) - like strain (A/Darwin/6/2021 IVR-227)

15 µg HA\*\*

B/Austria/1359417/2021 - like strain (B/Austria/1359417/2021 BVR-26)

15 µg HA\*\*

B/Phuket/3073/2013 - like strain (B/Phuket/3073/2013 BVR - 1B)

15 µg HA\*\*

per 0.5 ml dose

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\* propagated in fertilized hens' eggs from healthy chicken flocks and adjuvanted with MF59C.1

\*\* haemagglutinin