

**LABELING**  
**For FSME-IMMUN 0.5 ml**

**PARTICULARS TO APPEAR ON THE <OUTER PACKAGING>**

**BOX LABEL for FSME-IMMUN 0.5 ml**

**1. NAME OF THE MEDICINAL PRODUCT**

FSME-IMMUN 0,5 ml  
Suspension for injection in a pre-filled syringe  
Tick-Borne Encephalitis Vaccine (whole Virus inactivated)

**2. STATEMENT OF ACTIVE SUBSTANCE(S)**

One dose (0.5 ml) contains

Tick-Borne Encephalitis Virus (strain Neudörfl) 2.4 micrograms

adsorbed on aluminium hydroxide, hydrated (0.35 milligrams  $Al^{3+}$ )  
produced in chick embryo fibroblast cells (CEF cells)

**3. LIST OF EXCIPIENTS**

Human albumin, sodium chloride, disodium phosphate-dihydrate, potassium dihydrogen-phosphate, sucrose, water for injection.  
Sodium and potassium content – see Leaflet for further information.

**4. PHARMACEUTICAL FORM AND CONTENTS**

Suspension for injection in pre-filled syringe (without attached needle)  
(0.5 ml – pack sizes of 1, 10, 20 or 100)  
1 syringe 0.5 ml

**5. METHOD AND ROUTE(S) OF ADMINISTRATION**

Intramuscular use.  
Shake before use.  
Read the package leaflet before use.

**6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN**

Keep out of the sight and reach of children.

**7. OTHER SPECIAL WARNING(S), IF NECESSARY**

For persons of 16 years of age and older.  
Pfizer logo/text

**8. EXPIRY DATE**

EXP: MM/YYYY

**9. SPECIAL STORAGE CONDITIONS**

Store in a refrigerator.

Do not freeze.

Keep the syringe in the outer carton in order to protect from light.

**10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

**11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

To be completed nationally

**12. MARKETING AUTHORISATION NUMBER(S)**

To be completed nationally

**13. BATCH NUMBER**

LOT:

**14. GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product subject to medical prescription.

**15. INSTRUCTIONS ON USE**

**16. INFORMATION IN BRAILLE**

FSME-IMMUN 0.5 ml

**17. UNIQUE IDENTIFIER – 2D BARCODE**

2D barcode carrying the unique identifier included

**18. UNIQUE IDENTIFIER – HUMAN READABLE DATA**

PC:  
SN:  
NN:

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**  
**SYRINGE LABEL for FSME-IMMUN 0.5 ml**

**1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION**

FSME-IMMUN 0.5 ml  
Suspension for injection in a pre-filled syringe  
Tick-Borne Encephalitis Vaccine (whole Virus inactivated)  
Intramuscular use

**2. METHOD OF ADMINISTRATION**

IM

**3. EXPIRY DATE**

EXP MM/YYYY

**4. BATCH NUMBER**

LOT:

**5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT**

0.5 ml

**6. OTHER**

Pfizer Logo/Text (MAH)