

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 Neudörf) 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)