

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING**OUTER CARTON****1. NAME OF THE MEDICINAL PRODUCT**

Celvapan suspension for injection
Pandemic influenza vaccine (H1N1) (whole virion, Vero cell derived, inactivated)

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Whole virus influenza vaccine, inactivated containing antigen of pandemic strain*:

A/California/07/2009 (H1N1) 7.5 microgram**
per 0.5 ml dose

* propagated in Vero cells (continuous cell line of mammalian origin)

** expressed in micrograms haemagglutinin

3. LIST OF EXCIPIENTS

Trometamol,
sodium chloride,
water for injections,
polysorbate 80

4. PHARMACEUTICAL FORM AND CONTENTS

Suspension for injection.
20 multidose vials (10 doses per vial – 0.5 ml per dose)

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Intramuscular use.
The vaccine should be allowed to reach room temperature before use.
Shake before use.
After first opening, the vial is to be used within a maximum of 3 hours.

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

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Do not inject intravascularly.

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in refrigerator.

Do not freeze.

Store in the original package 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

Dispose of in accordance with local requirements.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Baxter AG
Industriestrasse 67
A-1221 Vienna
Austria

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/08/506/001

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE**16. INFORMATION IN BRAILLE**

Justification for not including Braille accepted.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS LABEL FOR 10-DOSE VIAL
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1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION
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Celvapan suspension for injection
Pandemic influenza vaccine (H1N1) (whole virion, Vero cell derived, inactivated)

Intramuscular use

2. METHOD OF ADMINISTRATION

Shake before use

3. EXPIRY DATE

EXP

4. BATCH NUMBER

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5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT
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Multidose vial (10 doses of 0.5 ml per vial)

6. OTHER

After first opening, the vial is to be used within a maximum of 3 hours.

BAXTER AG
A-1221 Vienna
Austria