A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING
PACK CONTAINING 1 PACK OF 10 VIALS OF SUSPENSION (ANTIGEN) AND 1 PACK OF 10 VIALS OF EMULSION (ADJUVANT)

1. NAME OF THE MEDICINAL PRODUCT

HUMENZA suspension and emulsion for emulsion for injection
Pandemic influenza vaccine (H1N1) (split virion, inactivated, adjuvanted)

2. STATEMENT OF ACTIVE SUBSTANCE(S)

After mixing, 1 dose (0.5 ml) contains:
Split influenza virus*, inactivated, containing antigen equivalent to:
A/California/7/2009 (H1N1)-like strain (NYMC X-179A).....3.8 micrograms**

* propagated in eggs
** haemagglutinin

AF03 adjuvant composed of squalene, sorbitan oleate, polyoxyethylene cetostearyl ether and mannitol

3. LIST OF EXCIPIENTS

Excipients:
Thiomersal
Sodium chloride
Potassium chloride
Disodium phosphate dihydrate
Potassium dihydrogen phosphate
Water for injections

4. PHARMACEUTICAL FORM AND CONTENTS

Suspension and emulsion for emulsion for injection
10 vials of suspension (antigen)
10 vials of emulsion (adjuvant)

Number of doses after mixing the content of antigen vial into the adjuvant vial: **10 doses** of 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 REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children

7. OTHER SPECIAL WARNING(S), IF NECESSARY

MIX THE ANTIGEN INTO THE ADJUVANT VIAL BEFORE USE

8. EXPIRY DATE

EXP MM/YYYY

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator. Do not freeze.
Keep the vials in the outer carton in order to protect from light.
After mixing, store in a refrigerator and use within 24 hours.

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 regulations.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Sanofi Pasteur SA
2, avenue Pont Pasteur
69007 Lyon - France

12. MARKETING AUTHORISATION NUMBER(S)

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

PARTICULARS TO APPEAR ON THE OUTER PACKAGING
PACK OF 10 VIALS OF SUSPENSION (ANTIGEN)

1. NAME OF THE MEDICINAL PRODUCT

Antigen for HUMENZA suspension for injection
Pandemic influenza vaccine (H1N1)

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Split influenza virus*, inactivated, containing antigen equivalent to:
A/California/7/2009 (H1N1)-like strain (NYMC X-179A).....30 µg**
For 1 ml

* propagated in eggs
** haemagglutinin

3. LIST OF EXCIPIENTS

Excipients: thiomersal, sodium chloride, potassium chloride, disodium phosphate dihydrate, potassium dihydrogen phosphate and water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

Suspension for injection
10 vials

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use
Read the package leaflet before use

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

MIX INTO THE ADJUVANT VIAL BEFORE USE

8. EXPIRY DATE

EXP MM/YYYY

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator. Do not freeze.
Keep the vials 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

Dispose of in accordance with local regulations.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Sanofi Pasteur SA
2, avenue Pont Pasteur
69007 Lyon - France

12. MARKETING AUTHORISATION NUMBER(S)

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

PARTICULARS TO APPEAR ON THE OUTER PACKAGING
PACK OF 10 VIALS OF EMULSION (ADJUVANT)

1. NAME OF THE MEDICINAL PRODUCT

Adjuvant for HUMENZA emulsion for injection

2. STATEMENT OF ACTIVE SUBSTANCE(S)

AF03 adjuvant composed of squalene (33 mg), sorbitan oleate (4.9 mg), polyoxyethylene cetostearyl ether (6.3 mg), mannitol (6.1 mg) per 1 ml

3. LIST OF EXCIPIENTS

Excipients: sodium chloride, potassium chloride, disodium phosphate dihydrate, potassium dihydrogen phosphate and water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

Emulsion for injection
10 vials
After mixing: 10 doses of 0.5 ml per vial.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

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

MIX WITH THE ANTIGEN BEFORE USE

8. EXPIRY DATE

EXP MM/YYYY

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator. Do not freeze.
Keep the vials in the outer carton in order to protect from light.
After mixing: use within 24 hours.

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 regulations.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Sanofi Pasteur SA
2, avenue Pont Pasteur
69007 Lyon - France

12. MARKETING AUTHORISATION NUMBER(S)

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 SUSPENSION VIAL (ANTIGEN)

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

Antigen for HUMENZA
Pandemic influenza vaccine (H1N1)

2. METHOD OF ADMINISTRATION

Mix into the adjuvant vial before use.

3. EXPIRY DATE

EXP MM/YYYY

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

1.5 ml

6. OTHER

Sanofi Pasteur

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
EMULSION VIAL (ADJUVANT)

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

Adjuvant for HUMENZA emulsion for injection
IM

2. METHOD OF ADMINISTRATION

3. EXPIRY DATE

EXP MM/YYYY

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

4.5 ml
After mixing with the antigen: 10 doses of 0.5 ml

6. OTHER

Sanofi Pasteur