Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Invivac 2005/2006, suspension for injection (influenza vaccine, surface antigen, inactivated, virosome).

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

- A/California/7/2004 (H3N2) like strain
(A/New York/55/2004 NYMC X-157 reass.) 15 microgram HA**

- A/New Caledonia/20/99(H1N1)-like
(A/New Caledonia/20/99 IVR-116 reass.) 15 microgram HA**

- B/Shanghai/361/2002- like strain
(B/Jiangsu/10/2003) 15 microgram HA** per 0.5 ml dose.

* propagated in fertilised hens' eggs from healthy chicken flocks
** haemagglutinin.

This vaccine complies with the WHO recommendation (northern hemisphere) and EU decision for the 2005/2006 season.

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Suspension for injection in prefilled syringes; a slightly opalescent liquid, filled in single-dose syringes (glass, type I).

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Prophylaxis of influenza, especially in those who run an increased risk of associated complications.

The use of Invivac 2005/2006 should be based on official recommendations.

4.2 Posology and method of administration

Adults: 0.5 ml.
Immunisation should be carried out by intramuscular or deep subcutaneous injection.
Children: the clinical data available are too limited to vaccinate children with Invivac.

For instructions for preparation, *see section 6.6.*

4.3 Contraindications

Hypersensitivity to the active substances, to any of the excipients and to residues of eggs, chicken protein (Invivac does not contain more than 0.5 µg ovalbumin per dose) or gentamicin.

Immunisation shall be postponed in patients with febrile illness or acute infection.

4.4 Special warnings and precautions for use

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine.

Invivac 2005/2006 should under no circumstances be administered intravascularly.

Antibody response in patients with endogenous or iatrogenic immunosuppression may be insufficient.

4.5 Interaction with other medicinal products and other forms of interaction

Invivac 2005/2006 may be given at the same time as other vaccines. Immunisation should be carried out on separate limbs. It should be noted that the adverse reactions may be intensified.

The immunological response may be diminished if the patient is undergoing immunosuppressant treatment.

Following influenza vaccination, false positive results in serology tests using the ELISA method to detect antibodies against HIV1, Hepatitis C and especially HTLV1 have been observed. The Western Blot technique disproves the false-positive ELISA test results. The transient false-positive reactions could be due to the IgM response by the vaccine.

4.6 Fertility, pregnancy and lactation

The limited data from vaccinations in pregnant women do not indicate that adverse fetal and maternal outcomes were attributable to the vaccine. The use of this vaccine may be considered from the second trimester of pregnancy. For pregnant women with medical conditions that increase their risk of complications from influenza, administration of the vaccine is recommended, irrespective of their stage of pregnancy.
Invivac 2005/2006 may be used during lactation.

4.7 Effects on ability to drive and use machines

Invivac 2005/2006 is unlikely to produce an effect on the ability to drive and use machines.

4.8 Undesirable effects

ADVERSE REACTIONS OBSERVED FROM CLINICAL TRIALS
The safety of trivalent inactivated influenza vaccines is assessed in open label, uncontrolled clinical trials performed as annual update requirement, including at least 50 adults aged 18 - 60 years of age and at least 50 elderly aged 61 years or older. Safety evaluation is performed during the first 3 days following vaccination.

The following undesirable effects have been observed during clinical trials with the following frequencies:

very common (>1/10); common (≥1/100, <1/10); uncommon (≥1/1000, <1/100); rare (≥1/10000, <1/1000); very rare (<1/10000), including isolated reports.

Organ class	Very common >1/10	Common ≥1/100, <1/10	Uncommon ≥1/1,000, <1/100	Rare ≥1/10,000, <1/1,000	Very rare <1/10,000
Nervous system disorders		Headache*			
Skin and subcutaneous tissue disorders		Sweating*			
Musculoskeletal and connective tissue disorders		Myalgia, arthralgia*			
General disorders and administration site conditions		fever, malaise, shivering, fatigue Local reactions: redness, swelling, pain, ecchymosis induration*			

* these reactions usually disappear within 1-2 days without treatment.

ADVERSE REACTIONS REPORTED FROM POST-MARKETING SURVEILLANCE

Adverse reactions reported from post marketing surveillance are, next to the reactions which have also been observed during the clinical trials, the following:

Blood and lymphatic system disorders:
Transient thrombocytopenia, transient lymphadenopathy

Immune system disorders:
Allergic reactions, in rare cases leading to shock, angioedema

Nervous system disorders:
Neuralgia, paraesthesia, febrile convulsions, neurological disorders, such as encephalomyelitis, neuritis and Guillain-Barré syndrome

Vascular disorders:
Vasculitis associated in very rare cases with transient renal involvement

Skin and subcutaneous tissue disorders:
Generalised skin reactions including pruritus, urticaria or non-specific rash

4.9 Overdose

Overdosage is unlikely to have any untoward effect.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Influenza vaccine, ATC Code: J07BB02
Seroprotection is generally obtained within 2 to 3 weeks. The duration of post-vaccinal immunity to homologous strains or to strains closely related to the vaccine strains varies but is usually 6 to 12 months.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
disodium phosphate dihydrate
potassium dihydrogen phosphate
lecithin
water for injections.

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf Life

1 year.

6.4 Special precautions for storage

Store at +2°C to +8°C (in a refrigerator). Do not freeze. Protect from light.

6.5 Nature and contents of container

0.5 ml suspension for injection in prefilled syringe (glass, type I), pack of 1 or 10.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Unused vaccine and other waste material should be disposed of in compliance with local rules for the disposal of products of this nature.

Invivac 2005/2006 should be allowed to reach room temperature before use.
Shake before use.

7 MARKETING AUTHORISATION HOLDER

Abbott Healthcare Products Ltd
Mansbridge Road
West End
Southampton
SO18 3JD
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 0108/028/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 08 October 2004

Date of last renewal: 10 June 2009

10 DATE OF REVISION OF THE TEXT

February 2011