SUMMARY OF PRODUCT CHARACTERISTICS

Influvac 2015

1. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

- A/California/7/2009 (H1N1)pdm09-like strain (A/California/7/2009, X-181)	15 micrograms HA **
- A/Switzerland/9715293/2013 (H3N2)-like strain (A/Switzerland/9715293/2013, NIB-88)	15 micrograms HA **
- B/Phuket/3073/2013-like strain (B/Phuket/3073/2013, wild type)	15 micrograms HA **
	per 0.5 ml dose

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

This vaccine complies with the WHO recommendation (southern hemisphere) and competent authority decision for the 2015 season.

For a full list of excipients see section 5.1.

Influvac 2015 may contain traces of eggs (such as ovalbumin, chicken proteins), formaldehyde, cetyltrimethylammonium bromide, polysorbate 80 or gentamicin, which are used during the manufacturing process (see section 3.3).

2. PHARMACEUTICAL FORM

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

3. CLINICAL PARTICULARS

3.1. Therapeutic indications

Prophylaxis of influenza, especially those who run an increased risk of associated complications.
Influvac 2015 is indicated in adults and children from 6 months of age.
The use of Influvac 2015 should be based on official recommendations.
Vaccination is particularly recommended for the following categories of patients, depending on national immunization policies:

- Persons aged ≥ 65 years, regardless their health condition.
- Adults and children with chronic disorders of the pulmonary or cardiovascular systems, including asthma.
- Adults and children with chronic metabolic diseases such as diabetes mellitus.
- Adults and children with chronic renal dysfunction.
- Adults and children with immunodeficiencies due to disease or immunosuppressant medication (e.g., cytostatics or corticosteroids) or radiotherapy.
- Children and teenagers (6 months – 18 years) who receive long-term acetylsalicylic acid containing medication, and might therefore be at risk for developing Reye's syndrome following an influenza infection.

3.2. Posology and method of administration

Posology
Adults: 0.5 ml.

Paediatric population
Children from 36 months onwards: 0.5 ml.
Children from 6 months to 35 months: Clinical data are limited. Dosages of 0.25 ml or 0.5 ml may be given. The dose given should be in accordance with existing national recommendations.
For children, who have not previously been vaccinated, a second dose should be given after an interval of at least 4 weeks.

Children less than 6 months: the safety and efficacy of Influvac 2015 in children less than 6 months have not been established. No data are available.

Method of Administration
Immunisation should be carried out by intramuscular or deep subcutaneous injection.

Precautions to be taken before handling or administrating the medicinal product:
For instructions for preparation of the medicinal product before administration, see section 5.6.

3.3. Contraindications
Hypersensitivity to the active substances, to any of the excipients or to any component that may be present as traces such as eggs (ovalbumin, chicken proteins), formaldehyde, cetyltrimethylammonium bromide, polysorbate 80 or gentamicin.

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

3.4. 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.

Influvac 2015 should under no circumstances be administered intravascularly.

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

Interference with serological testing: see section 3.5.

3.5. Interaction with other medicinal products and other forms of interaction

Influvac 2015 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.

3.6. Fertility, pregnancy and lactation

Pregnancy
Inactivated influenza vaccines can be used in all stages of pregnancy. Larger datasets on safety are available for the second and third trimester, compared with the first trimester; however, data from worldwide use of influenza vaccine do not indicate any adverse foetal and maternal outcomes attributable to the vaccine.

Breastfeeding
Influvac 2015 may be used during breastfeeding.

Fertility
No fertility data are available

3.7. Effects on ability to drive and use machines

Influvac 2015 has no or negligible influence on the ability to drive and use machines.

3.8. 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).

Tabulated list of adverse reactions:

Organ class	Very common ≥1/10	Common ≥1/100, <1/10	Uncommon ≥1/1,000, <1/100
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

3.9. Overdose

Overdosage is unlikely to have any untoward effect.

4. PHARMACOLOGICAL PROPERTIES

4.1. Pharmacodynamic properties

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

4.2 Pharmacokinetic properties

Not applicable.

4.3 Preclinical safety data

Not applicable.

5. PHARMACEUTICAL PARTICULARS

5.1 List of excipients

Potassium chloride, potassium dihydrogen phosphate, disodium phosphate dihydrate, sodium chloride, calcium chloride dihydrate, magnesium chloride hexahydrate and water for injections.

5.2 Incompatibilities

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

5.3 Shelf-life

1 year.

5.4 Special precautions for storage

Store in a refrigerator **(**+2°C to +8°C**)**.
Do not freeze.
Store in the original package in order to protect from light.

5.5 Nature and contents of the container

0.5 ml suspension for injection in prefilled syringe with / without needle (glass, type I), pack of 1 or 10.

5.6 Special precautions for disposal and other handling

The vaccine should be allowed to reach room temperature before use.
Shake before use. Inspect visually prior to administration.

For the administration of a 0.25 ml dose from a single dose 0.5 ml syringe, push the front side of the plunger exactly to the edge of the mark so that half of the volume is eliminated; a volume of 0.25 ml of the vaccine remains in the syringe, suitable for administration. See also section 3.2.

Any unused product or waste material should be disposed of in accordance with local requirements.

6. NAME AND PERMANENT ADDRESS OF OFFICIAL PLACE OF ESTABLISHMENT OF THE HOLDER OF THE MARKETING LICENCE

Abbott Biologicals B.V.
C.J. van Houtenlaan 36
1381 CP Weesp
The Netherlands

Manufacturer:
Abbott Biologicals B.V.
Veerweg 12
8121 AA Olst
The Netherlands

7. DATE OF APPROVAL/REVISION OF THIS TEXT

November 2014