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influvac® 2011/2012

1. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

- A/California/7/2009 (H1N1):derived strain used reass. virus NYMC X-181 15 micrograms HA**
- A/Perth/16/2009 (H3N2): like strain used reass. virus NYMC X-187 derived from A/Victoria/210/2009 15 micrograms HA**
- B/Brisbane/60/2008 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 (northern hemisphere) and competent authority decision for the 2011/2012 season.

For a full list of excipients see section 5.1.

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

Prevention of influenza; especially in those who run an increased risk of associated complications. The use of Influvac 2011/2012 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

Adults and children from 36 months: 0.5 ml.
Children from 6 months to 35 months: Clinical data are limited. Dosages of 0.25 ml or 0.5 ml have been used.
For children who have not previously been vaccinated, a second dose should be given after an interval of at least 4 weeks.

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

For instructions for preparation, see section 5.6.

3.3 Contraindications

Hypersensitivity to the active substances, to any of the excipients and to residues of eggs, chicken protein (such as ovalbumin), formaldehyde, cetyltrimethylammonium bromide, polysorbate 80, or gentamicin.

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

3.4 Special warnings and special 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 2011/2012 should under no circumstances be administered intravascularly.

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

3.5 Interaction with other medicinal products and other forms of interaction

Influvac 2011/2012 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 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.
Influvac 2011/2012 may be used during lactation.

3.7 Effects on ability to drive and use machines

Influvac 2011/2012 is unlikely to produce an effect 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 (≥1/100, <1/1000); rare (≥1/10000, <1/1000); very rare (<1/10000), including isolated reports.

Organ class	Very common ≥1/10	Common ≥1/100 <1/10	Uncommon ≥1/1000, <1/100	Rare ≥1/10000, <1/1000	Very rare <1/10000
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, febril 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 post-vaccinal immunity to homologuous 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 compatability 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 at +2°C to +8°C (in a refrigerator).
Do not freeze.
Protect from light.

5.5 Nature and contents of container
0.5 ml suspension for injection in prefilled syringe (glass, type I), pack of 1 or 10.

5.6 Special precautions for disposal and other handling
Influvac 2011/2012 should be allowed to reach room temperature before use.
Shake before use.
For administration of a 0.25 ml dose from a syringe, push the front side of the plunger exactly to the edge of the hub (the knurled polypropylene ring); a reproducible volume of vaccine remains in the syringe, suitable for administration.

Any unused product or waste material should be disposed of in accordance with local requirements. See section 3.2.

6. NAME AND PERMANENT ADDRESS OF OFFICIAL PLACE OF ESTABLISHMENT OF THE HOLDER OF THE MARKETING LICENSE
Abbott Biologicals B.V.
C.J. van Houtenlaan 36
NL-1381 CP Weesp
The Netherlands

7. **DATE OF APPROVAL/REVISION OF THIS TEXT**
April 2011