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
- A/Perth/16/2009 (H3N2): like strain used reass. virus NYMC X-187 derived from
- A/Victoria/210/2009
- B/Brisbane/60/2008

per 0.5 ml dose.

* propagated in fertilised hens' eggs from healthy chicken flocks

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

2.1 Container

Packaged in 0.5ml prefilled glass syringes. Each syringe contains 15 micrograms of inactivated haemagglutinin (HA) of the following strains:
- A/Perth/16/2009 (H3N2): like strain used reass. virus NYMC X-187 derived from
- A/Victoria/210/2009
- B/Brisbane/60/2008

2.2 Pharmaceutical particulars

Sanctions for injection: (≥1/10000, <1/1000); very rare (<1/10000), including isolated reports.

- 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., cyclosporin 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 Raye's syndrome following an influenza infection.

3. CLINICAL PARTICULARS

3.1 Therapeutic indications

Prevention of influenza virus infection, especially in those who run an increased risk of associated complications. The use of Influvac 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., cyclosporin 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 Raye's syndrome following an influenza infection.

3.2 Posology and method of administration

Adults and children from 3 months: 0.5 ml.
Children from 6 months to 36 months: Clinical data are limited. Dosages of 0.25 ml or 0.5 ml may have been used.

3.3 Contraindications

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

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 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

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:

- Adults and children from 3 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.
- Influvac 2012 may be used during lactation.

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. Administration of the vaccine is recommended, irrespective of their stage of pregnancy.

3.7 Effects on ability to drive and use machines

Influvac 2012 may be used during lactation.

3.8 Undesirable effects

ADVERSE REACTIONS OBSERVED FROM CLINICAL TRIALS

The safety of Influvac 2012 has been evaluated in all batches produced. The safety of Influvac 2012 has been evaluated in all batches produced. The safety of Influvac 2012 has been evaluated in all batches produced. The safety of Influvac 2012 has been evaluated in all batches produced. The safety of Influvac 2012 has been evaluated in all batches produced. The safety of Influvac 2012 has been evaluated in all batches produced. The safety of Influvac 2012 has been evaluated in all batches produced. The safety of Influvac 2012 has been evaluated in all batches produced. The safety of Influvac 2012 has been evaluated in all batches produced. The safety of Influvac 2012 has been evaluated in all batches produced. The safety of Influvac 2012 has been evaluated in all batches produced. The safety of Influvac 2012 has been evaluated in all batches produced. The safety of Influvac 2012 has been evaluated in all batches produced. 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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
- 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 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 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 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 knurted polypropylene ring); a reproducible volume of vaccine remains in the syringe, suitable for administration. See 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 LICENSE

Abbott Biologicals B.V.
C.J. van Houtenlaan 38
NL-1381 CP Weesp
The Netherlands

7. DATE OF APPROVAL/REVISION OF THIS TEXT

November 2011
Customer Approval:
Document entirely checked and approved for implementation

Name: 
Job Title: 
Country: 
Date: 
Signature: 

Technical Approval: 

Name: 
Signature: 

Check pharmacode in SAP: 

Printer information: 

SAP number: 1079006 
Replaces in time: 1074369 
Print date: 31-10-2010 version:01 
LTS: 1 - 0 - 7 
Die cut/dimensions: 120 x 360 mm (folded to size 120 x 23 mm) 
Pharmacode: 74 
Colours: black 
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Made by: Richard van Zanten