

Registration No......2B 4/48 (N)

Importer / Manufacturer: GPO-MBP

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICAL PRODUCT

INFLUENZA VACCINE

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Influenza virus (inactivated, split) of the following strains*:

A/California/7/2009 (H1N1) – derived strain used NYMX X-179A..... 15 mcg HA**

A/Perth/16/2009 (H3N2) – like strain used NYMC X-187 derived from
A/Victoria/210/2009..... 15 mcg HA**

B/Brisbane/60/2008..... 15 mcg HA**

Per 0.5 ml dose

* Propagated in fertilized hens' eggs from healthy chicken flocks

** Haemagglutinin

This vaccine complies with the WHO recommendations (Southern Hemisphere) for the 2012 season.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection in multidose vial.

The vaccine, after shaking gently, is a slightly whitish and opalescent liquid.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Prophylaxis of influenza, especially in subjects who run a high risk of associated complications.

The use of this vaccine should be based on official recommendations.

4.2 Posology and method of administration

Adults and children from 36 months: 0.5 ml.

Children from 6 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.

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

For instructions for preparation, see section 6.6.

4.3 Contraindication

Hypersensitivity to the active substances, to any of the excipients including thiomersal and to residues e.g. from eggs, such as ovalbumin, chicken proteins.

The vaccine may contain other residues of the following substances: neomycin, formaldehyde and octoxinol 9.

Vaccination shall be postponed in case of febrile illness or acute infection.

4.4 Special warnings and precautions for use

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

INFLUENZA VACCINE should under no circumstances be administered intravascularly.

Antibody response in patients with congenital or acquired immunosuppression may be insufficient.

4.5 Interaction with other medical products and forms of interaction

INFLUENZA VACCINE may be given at the same time as other vaccines. However, injections should be carried out on separate limbs. It should be noted that the adverse reactions may be intensified.

The immune 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 these transient false-positive reactions, which may be due to the IgM response induced by vaccination.

4.6 Pregnancy and lactation

The limited data from vaccinations in pregnant women do not indicate that adverse foetal and maternal events are attributable to the vaccine. The use of this vaccine may be considered from the second trimester of pregnancy. For pregnant women who run a high risk of complications associated with influenza, administration of the vaccine is recommended, irrespective of their stage of pregnancy.

The vaccine may be used during lactation

4.7 Effects on the ability to drive and use machines

The vaccine 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 regulatory 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 ($\geq 1/10$); common ($\geq 1/100$; $<1/10$); uncommon ($\geq 1/1\ 000$; $<1/100$); rare ($\geq 1/10\ 000$; $<1/1\ 000$); very rare ($<1/10\ 000$), including isolated reports.

| Organ class | Very common ($\geq 1/10$) | Common ($\geq 1/100$; $<1/10$) | Uncommon ($\geq 1/1\ 000$; $<1/100$) | Rare ($\geq 1/10\ 000$; $<1/1\ 000$) | 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:

Generalized skin reactions including pruritus, urticaria or non-specific rash

This vaccine contains thiomersal (an organomercuric compound) as a preservative and therefore, hypersensitivity reactions may occur (see section 4.3).

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 postvaccinal immunity to homologous strains or to strains closely related to the vaccine strains varies but is usually 6-12 months.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Thiomersal and buffer solution containing sodium chloride, disodium phosphate dihydrate, potassium dihydrogen phosphate, potassium chloride and water for injections.

6.2 Incompatibilities

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

6.3 Shelf life

1 year.

6.4 Special precautions for storage

Store in a refrigerator (2°C – 8°C). Do not freeze.

Keep the vial in the outer carton in order to protect from light.

6.5 Nature and contents of container

Vial: Type I Borosilicate glass

6.6 Special precautions for disposal and other handling

The vaccine should be brought to room temperature before use.

Shake before use.

The vaccine should not be used if foreign particles are present in the suspension.

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

7. MARKETING AUTHORISATION HOLDER

Government Pharmaceutical Organization – Mérieux Biological Products Co., Ltd.

8. MARKETING AUTHORISATION NUMBER(S)

2B 4/48 (N)

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

19 September 2005

10. DATE OF REVISION OF THE TEXT

June 2012