Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Begrivac 2010/2011 suspension for injection
Influenza vaccine (split virion, inactivated)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

A/California/7/2009 (H1N1) – derived strain used
NYMC X-181 15.0 micrograms HA **

A/Perth/16/2009 (H3N2) – like strain used 15.0 micrograms HA **
NYMC X-187 – derived from A/Victoria/210/2009

B/Brisbane/60/2008 – derived strain used 15.0 micrograms HA **
NYMC BX-35

per 0.5 ml dose
*propagated in fertilized hen eggs from healthy chicken flocks, purified, split by tween-ether, inactivated by formaldehyde

**haemagglutinin
The vaccine complies with the WHO recommendation (northern hemisphere) and EU decision for the 2010/2011 season.

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Suspension for injection in pre-filled syringe.
Slightly opalescent.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

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

The use of Begrivac 2010/2011 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 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 6.6.

4.3 Contraindications

Hypersensitivity to the active substances, to any of the excipients and to eggs, chicken protein, formaldehyde, diethyleter or polysorbate 80.

Begrivac 2010/2011 does not contain more than 1.0 µg ovalbumin per dose. The vaccine may contain residues of polymyxin B.

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.

Begrivac 2010/2011 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

Begrivac 2010/2011 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 immuno-suppressant 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.
Begrivac 2010/2011 may be used during lactation.

4.7 Effects on 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 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 (≥ 1/1,000, < 1/100); rare (≥ 1/10,000, < 1/1,000); very rare (< 1/10,000), including isolated reports.

Nervous system disorders

Common: Headache*

Skin and subcutaneous tissue disorders

Common: Sweating*

Musculoskeletal and connective tissue disorders

Common: Myalgia, arthralgia*

General disorders and administration site conditions

Common: 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

Vacsular 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 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

Buffer solution (pH = 7.2) containing: sodium chloride, potassium chloride, magnesium chloride hexahydrate, disodium phosphate dihydrate, potassium dihydrogen phosphate and 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 in a refrigerator (2 °C – 8 °C). Do not freeze. Keep the syringe in the outer carton in order to protect from light.

6.5 Nature and contents of container

0.5 ml suspension in pre-filled syringe (Type I glass) with plunger stopper (bromobutyl rubber) with or without needle – in pack sizes of 1, 10 or 20 (2 × 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

The vaccine should be allowed to reach room temperature before use.
Shake before use.

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

7 MARKETING AUTHORISATION HOLDER

Novartis Vaccines and Diagnostics GmbH
P.O. Box 1630
D-35006 Marburg
Germany

8 MARKETING AUTHORISATION NUMBER

PA 0877/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 3 April 1998

Date of last renewal: 30 December 2007

10 DATE OF REVISION OF THE TEXT

November 2010