

## PHYSICIAN INFORMATION LEAFLET

### 1. TRADE NAME OF THE MEDICINAL PRODUCT

Begrivac® 2007/2008 / suspension for injection in pre-filled syringe  
Influenza vaccine (split virion, inactivated)

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Split influenza virus, inactivated, containing antigens equivalent to\*:

A/Solomon Islands/3/2006 (H1N1) - like strain used (A/Reass. IVR-145) .....15 micrograms\*\*  
A/Wisconsin/67/2005 (H3N2) - like strain used (A/Wisconsin/67/2005, NYMC X161B)...15 micrograms\*\*  
B/Malaysia/2506/2004 - like strain used (B/Malaysia/2506/2004) .....15 micrograms\*\*  
per 0.5 ml dose

\* propagated in embryonated hen eggs, purified, split by tween-ether, inactivated by formaldehyde \*\* haemagglutinin

This vaccine complies with the WHO recommendation (northern hemisphere) and EU decision for the 2007/2008 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 2007/2008 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 Contra-indications

Hypersensitivity to the active substances, to any of the excipients, or to eggs, chicken protein, formaldehyde, diethylether, polysorbate 80.  
Begrivac® 2007/2008 does not contain more than 1,0 µg of 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 Special Precautions for Use

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of anaphylactic event following the administration of the vaccine.  
Begrivac® 2007/2008 should under no circumstances be administered intravascularly.

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

### 4.5 Interactions with other Medicaments and other forms of Interaction

Begrivac® 2007/2008 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 test results. The transient false positive reactions could be due to the IgM response by the vaccine.

### 4.6 Pregnancy and Lactation

The limited data from vaccinations in pregnant women do not indicate that adverse foetal 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® 2007/2008 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.

## PATIENT INFORMATION LEAFLET

# BEGRIVAC® 2007/2008

## Influenza vaccine (split virion, inactivated)

Please read this carefully before you receive your medicine. This leaflet only provides a summary of the information available on your medicine. If you have any questions, or are not sure about anything, ask your doctor or pharmacist.

### WHAT IS BEGRIVAC?

Begrivac is a vaccine against influenza. It is prepared in hen's eggs. It contains influenza virus antigens\* together with sodium chloride, potassium chloride, magnesium chloride hexahydrate, disodium phosphate dihydrate, potassium dihydrogen phosphate, sucrose and water for injections. Polymyxin B (antimicrobial agent), formaldehyde, diethylether and polysorbate 80 may be present in traces.

\*The appropriate antigens for 2007/2008 are:

A/Solomon Islands/3/2006 (H1N1) - like strain (A/Reass. IVR-145).....15 micrograms

A/Wisconsin/67/2005 (H3N2) - like strain

(A/Wisconsin/ 67/2005, NYMC X161B)..15 micrograms

B/Malaysia/2506/2004 - like strain

(B/Malaysia/ 2506/2004).....15 micrograms

Begrivac is supplied in pre-filled syringes as a 0.5 ml suspension for injection.

The Product Licence Holder and manufacturer of Begrivac is Novartis Vaccines and Diagnostics GmbH & Co. KG, 35006 Marburg, Germany.

### WHY USE BEGRIVAC?

Begrivac is used to give active immunisation against influenza.

The use of Begrivac 2007/2008 should be based on official recommendations.

### BEFORE YOU ARE VACCINATED

Tell the doctor or nurse if you are taking any other medicines.

Make sure that you have told the doctor or nurse everything about your medical history and of any problems you may have had with taking medicines in the past especially if you have reacted badly to a vaccination or if you are allergic to eggs, chicken protein or any other ingredients of the vaccine.

Tell the doctor or nurse if you are or think you may be pregnant or are breast-feeding.

Tell your doctor if you are having immunosuppressive therapy e.g., chemotherapy for cancer or corticosteroid treatment, or have any condition which makes you prone to get a lot of infections (immunodeficiency condition).

### HOW SHOULD I USE BEGRIVAC?

The vaccine will be given to you by a doctor or nurse.

The usual dose for adults and children from 36 months is one injection of 0.5 ml which may be given into the muscle or deep under the skin of the upper arm. For children from 6 to 35 months usually 0.25 ml should be injected (the clinical data available for this age range is limited).

For children who have not previously been vaccinated, a second dose should be given after an interval of at least 4 weeks.

The vaccination can only protect against virus influenza. Influenza-like diseases can be caused by other germs and 'flu vaccination will not prevent these.

### WHAT UNDESIRABLE EFFECTS MAY BEGRIVAC CAUSE?

Any medicine can have side-effects.

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 single reports.

Nervous system disorders

*Common:* Headache\*

Skin and subcutaneous tissue (under the skin) disorders

*Common:* Sweating\*

Musculoskeletal and connective tissue disorders

*Common:* Muscle pain, joint pain\*

General disorders and administration site conditions

*Common:* Fever, malaise, shivering, tiredness. Local reactions: redness, swelling, pain, bruising, hardening.\*

\*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:

Non-persisting low platelet count in the blood, non-persisting swelling of lymph glands

Immune system disorders:

Allergic reactions, in rare cases leading to shock, swelling of skin and mucosae, often in the face

Nervous system disorders:

Painful irritation of the nerves, numbness and tingling sensation, fever cramps, inflammation of brain and spinal cord, painful inflammation of a nerve and Guillain Barré syndrome (a type of paralysis).

Vessel disorders:

Inflammation of the blood vessels associated in very rare cases with kidney problems

Skin and subcutaneous tissue disorders:

Skin reactions on the whole body including itching, bumps on the skin or non-specific rash.

If you feel ill or notice anything unusual or unexpected after your vaccination, tell your doctor.

#### HOW SHOULD I STORE BEGRIVAC?

Store in a refrigerator at 2°C to 8°C. Do not freeze. Keep the syringe in the outer carton to protect from light.

It should not be used after the expiry date shown on the label.

**Keep this medicine in a safe place where children cannot reach it.** Your medicines could harm them.

**Remember** this medicine is for **you**. Only a doctor can prescribe it for you. **Never** give it to others. It may harm them, even if they have the same symptoms as you.

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist, who have access to additional information.

This leaflet only applies to Begrivac.

Last revision: May 2007

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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 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.

#### 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.

The preparation is free of preservatives.

##### 5.2 Pharmacokinetic Properties

Not applicable.

##### 5.3 Preclinical Safety Data

Not applicable.

#### 6. PHARMACEUTICAL PARTICULARS

##### 6.1 List of Excipients

Sucrose, 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 Containers

0.5ml suspension in type I glass pre-filled syringe with a bromobutyl rubber plunger stopper, with/without needle - pack sizes of 1, 10 or 20 (2 x 10).

Not all of the licenced pack sizes are necessarily marketed in all countries.

#### 6.6 Instructions for Use/Handling

Unused vaccine and other waste material should be disposed of in compliance with local rules for the disposal of product of this nature.

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

Shake before use.

For children, when a dose of 0.25 ml is indicated, the following procedure is recommended:

Syringe without mark for the 0.25 ml dose:

The pre-filled syringe should be held in the upright position and half of the volume should be eliminated. The remaining volume should be injected.

Syringe with a mark for the 0.25 ml dose:

Discard half the contained volume up to the mark (little black line indicated on the syringe barrel below the label), before injection.

#### 7. MARKETING AUTHORISATION HOLDER

Novartis Vaccines and Diagnostics GmbH & Co. KG  
P.O. Box 1630, 35006 Marburg, Germany

#### 8. MARKETING AUTHORISATION NUMBER

PL 16033/0006  
PA 877/1/1  
MRP: DE/H/125/01

#### 9. DATE OF FIRST AUTHORISATION

UK: 23 March 1998  
Ireland: 3 April 1998 / 3 April 2003

#### 10. DATE OF PARTIAL REVISION OF TEXT

May 2007

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