Registration No. 2C 1/42 (N)

Importer / Manufacturer: Biogenetech Co., Ltd. / Novartis vaccine Diagnostics S.r.l.

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICAL PRODUCT
AGRIPPAL S1

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
One dose (0.5 ml) contains: **Active ingredients***:* Influenza virus surface antigens (haemagglutinin and neuraminidase), propagated in fertilized hen's eggs from healthy chicken flocks, and inactivated with formaldehyde, of the following strains:

A/California/07/2009 (H1N1)-like strain	
(A/California/07/2009, NYMC X-181)	15 micrograms HA*
A/Perth/16/2009 (H3N2)-like strain	
(A/Victoria/210/2009, NYMC X-187)	15 micrograms HA*
B/Brisbane/60/2008-like strain	
(B/Brisbane/60/2008)	15 micrograms HA*

* haemagglutinin

Excipients: sodium chloride; potassium chloride; potassium dihydrogen phosphate; disodium phosphate dihydrate; magnesium chloride hexahydrate; calcium chloride dihydrate and water for injection.
This vaccine complies with the WHO recommendations (southern hemisphere) for the 2011 season.

3. PHARMACEUTICAL FORM
Suspension for injection in pre-filled syringe. The vaccine appears as a clear liquid.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
Prophylaxis of influenza (flu), especially in those who run an increased risk of associated complications. The use of AGRIPPAL S1 should be based on official recommendations..

4.2 Posology and method of administration
Posology
- Adults and children over 36 months of age: 0.5ml
- Children from 6 to 35 months of age: clinical data are limited. Doses of 0.25 ml or 0.5 ml have been used.

Method of administration
For children who have not previously been vaccinated, a second dose should be given after an interval of at least 4 weeks.
If half a dose (0.25 ml) is to be administered, discard half the contained volume (up to the mark indicated on the syringe barrel), before injection. Immunisation should be carried out by intramuscular or deep subcutaneous injection.
The vaccine should be allowed to reach room temperature before use. Shake before use. 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.

.

4.3 Contraindication

Hypersensitivity to the active substances, to any of the excipients and to residues, e.g. eggs, chicken proteins, such as ovalbumin.
The vaccine may contain residues of the following substances, e.g. kanamycin and neomycin sulphate, formaldehyde, cetyltrimethylammonium bromide (CTAB) and polysorbate 80.
Immunisation shall be postponed in patients with febrile illness or acute infection.

4.4 Specials warnings and precautions for use

Special warnings: Antibody response in patients with endogenous (due to illness) or iatrogenic (due to medicine) immunosuppression (poor immune response) may be insufficient.
Precaution for use: As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event following the administration of the vaccine.
AGRIPPAL S1 should under no circumstances be administered intravascularly.

4.5 Interaction with other medical products and forms of interaction

AGRIPPAL S1 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 (blood test) to detect antibodies against HIV1, Hepatitis C and especially HTLV1 have been observed. The Western Blot technique disproves the false-positive ELISA 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. AGRIPPAL S1 may be used during lactation.

4.7 Effects on the ability to drive and use machines

AGRIPPAL S1 is unlikely to produce an effect on the ability to drive and use machines.

4.8 Undesirable effects

Like all medicines AGRIPPAL S1 can have side effects, although not everybody gets them.
Adverse reactions observed from clinical trials.
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.

<u>Nervous system disorders</u>

Common (≥1/100, <1/10):
Headache*

Skin and subcutaneous tissue disorders
Common (≥1/100, <1/10):
Sweating*

Musculoskeletal and connective tissue disorders
Common (≥1/100, <1/10):
Myalgia (muscular pain), arthralgia (joint pain)*

General disorders and administration site conditions
Common (≥1/100, <1/10):
Fever, malaise (generally feeling unwell), shivering, fatigue.
Local reactions: redness, swelling, pain, ecchymosis (bruising), induration (hardness).*

*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 (temporary reduction in the number of certain types of particles in the blood called platelets; a low number of these can result in excessive bruising or bleeding), transient lymphadenopathy (temporary swelling of the glands in the neck, armpit or groin)

Immune system disorders:
Allergic reactions, in rare cases leading to shock (medical emergency with a failure of the circulatory system to maintain adequate blood flow to the different organs), angioedema (swelling most apparent in the head and neck, including the face, lips, tongue, throat or any other part of the body).

Nervous system disorders:
Neuralgia (pain situated on the nerve route), paraesthesiae (anomalies in the perception of touch, pain, heat and cold), febrile convulsions (fits associated with fever), neurological disorders, such as encephalomyelitis, neuritis and Guillain-Barré syndrome (neurological disorders that may result in stiff neck, confusion, numbness, pain and weakness of the limbs, loss of balance, loss of reflexes, paralysis of part or all the body).

Vascular disorders:
Vasculitis (blood vessel inflammation which may result in skin rashes) associated in very rare cases with transient renal involvement.

Skin and subcutaneous tissue disorders:
Generalised skin reactions including pruritus, urticaria or non-specific rash.

These undesirable effects are generally transient. When they appear it is advisable to consult a physician. It is important to inform the physician of the appearance of any undesirable effects not described on this leaflet.

4.9 Overdose
Overdosage is unlikely to have any untoward effect.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
N/A

5.2 Pharmacokinetic properties
N/A

5.3 Preclinical safety data
N/A

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
AGRIPPAL S1 does not contain more than 0.4 µg of ovalbumin per ml.

6.2 Incompatibilities
N/A

6.3 Shelf life
1 year

6.4 Special precautions for storage
In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products. Do not use AGRIPPAL S1 after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month. AGRIPPAL S1 must be stored in a refrigerator (2°C - 8°C).

Do not freeze. Keep the syringe in the outer carton in order to protect from light. Any unused product or waste material should be disposed of in accordance with local requirements. Information regarding the medicinal product should always be kept at hand, therefore keep both the box and the package leaflet. Keep out of the reach and sight of children.

.

6.5 Nature and contents of container
Pre-filled syringe of one dose (0.5 ml) in box of 1 or 10.

6.6 Special precautions for disposal and other handling
N/A

7. MARKETING AUTHORISATION HOLDER
Biogenetech Co., Ltd.
18 Soi Udomsuk 37, Sukhumvit 103 Rd., Bangjak, Prakanong, Bangkok, 10260 THAILAND

8. MARKETING AUTHORISATION NUMBER(S)
2C 1/42 (N)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

September 11, 2002

10. DATE OF REVISION OF THE TEXT

January 28, 2010