Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

CadiFlu-S

Trivalent Seasonal Influenza Virus Like Particle (VLP) Vaccine

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.5 mL dose of CadiFlu-S contains 15 µg each of the haemagglutinin antigen of influenza A/California/04/2009 (H1N1); A/Victoria/361/2011 (H3N2); and B/Massachusetts/02/2012.
* purified VLP protein produced in Sf9 cells using recombinant baculovirus

CadiFlu-S contains no egg proteins or antibiotics.

For a full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM

Sterile liquid for Intramuscular Injection

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

CadiFlu-S is indicated for active immunization of adults 18 years of age and above against disease caused by influenza virus subtypes A and type B contained in the vaccine.

4.2 Posology and method of administration

CadiFlu-S should be administered as a single 0.5-mL intramuscular injection in the region of the deltoid muscle

Do not mix with other vaccines in the same syringe or vial.

4.3 Contraindications

CadiFlu-S is contraindicated in individuals with known severe allergic reactions (e.g anaphylaxis), to vaccine or any component of the vaccine.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed with CadiFlu-S.

4.8 Undesirable effects

Safety of CadiFlu-S has been evaluated during Phase-I/II and Phase III clinical studies in an Indian population. CadiFlu-S was found to be safe and well tolerated in both clinical trials. There was no significant difference in adverse event profile between the vaccine and placebo arms. The most common adverse events reported were local (injection) site pain, headache, cough, muscle pain, tiredness and sore throat.

Most of the reported AEs were mild in nature.

4.9 Overdose

No data are available on overdose with CadiFlu-S.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Influenza viruses have 2 major envelope glycoproteins - haemagglutinin (HA) and neuraminidase (NA), and protection against clinical disease is mainly conferred by serum antibodies to these glycoproteins. HA is the major antigenic target of virus neutralizing antibodies. Antibody to HA blocks the attachment of virus to cell surfaces, and is measured by the ability of serum to inhibit the agglutination of red blood cells by virus, termed haemagglutination-inhibition or HAI. Administration of this vaccine results in humoral antibody responses against the vaccine strain, A/California/07/2009 (H1N1), A/Victoria/361/2011 (H3N2) and B/Massachusetts/02/2012 manifested by increases in the serum titre of HAI antibodies.

Immunogenicity:

The immunogenicity endpoints for the Phase III trial (n=450) were evaluated based on HAI antibody titre analyzed in blood samples collected at pre-vaccination (day-0) and post-vaccination (day-21) time points. The immunogenicity endpoints included seroprotection rate, seroconversion rate and geometric mean fold rise. Seroprotection was defined as percentage of the subjects achieving a HAI antibody titre ≥40. Seroconversion was defined as percentage of subjects with either pre-vaccination titre < 10 and post vaccination HAI titre ≥40, or pre-vaccination HAI titre ≥10 and 4-fold rise in post vaccination titre. Geometric mean fold rise was defined as the ratio of post and pre-vaccination geometric mean titres.

Three strains, A/California/04/2009 (H1N1), A/Victoria/361/2011 (H3N2) and B/Massachusetts/02/2012 were studied in the Phase III trial. Seroprotection rate (≥70%)

6.5 Nature and contents of container

2 ml, 13 mm neck USP Type I glass vial with rubber stopper and flip off seal containing 0.5 mL – Single dose vial

6.6 Special precautions for disposal

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

7. MARKETING AUTHORISATION / PREQUALIFICATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

Not assigned

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

Authorisation awaited