SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

CADIFLU-S

Cadiflu-S is a Trivalent Seasonal Influenza Virus Like Particle (VLP) Vaccine containing HA, NA and M1 protein for corresponding strains. VLPs are structurally similar to a virus without the genetic material required for viral replication; thus, present no threat of infection to the person being vaccinated.

Cadiflu-S is a Halal certified Influenza vaccine and contains no egg proteins or animal products.

It does not contain preservatives or antibiotics.

2. COMPOSITION:

Each 0.5 mL dose of Trivalent Seasonal Influenza VLP vaccine contains 15 µg Haemagglutinin Antigen each of an A/Wisconsin/588/2019 (H1N1)pdm09-like virus; an A/Darwin/6/2021 (H3N2)-like virus; a B/Austria/1359417/2021 (B/Victoria lineage)-like virus in a phosphate buffer containing calcium chloride dihydrate, polysorbate 80, disodium hydrogen phosphate anhydrous, sodium dihydrogen phosphate monohydrate, sodium chloride and water for injection.

3. PHARMACEUTICAL FORM

Sterile liquid vaccine 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.

Vaccination is highly recommended for immunisation of health care workers, pregnant women, elderly population and people with specific underlying health conditions such as COPD or asthma, cardiac disease, chronic metabolic disorders (such as diabetes) and compromised immune status.

4.2 Posology and method of administration:

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

Do not mix Cadiflu-S with other vaccines in the same syringe or vial prior to vaccination.

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.

4.4 Special warnings and precautions for use:

Limitation of vaccine effectiveness:

The vaccine can only be expected to protect against influenza caused by the influenza virus subytpes A and type B contained in the vaccine. Vaccination may not protect all vaccine recipients.

Preventing and managing allergic reactions:

Prior to administration, the healthcare provider should review the individual's prior immunization history for possible adverse effects, to determine the existence of any contraindication to immunization with Cadiflu-S vaccine and to allow an assessment of benefits and risks.

Appropriate medical treatment and medical supervision must be available to manage possible anaphylactic reactions following administration of the vaccine.

An increased risk of Guillain-Barré syndrome has been reported in association with influenza immunization. In individuals who have a history of Guillain-Barré syndrome, the decision to give Cadiflu-S should be based on careful consideration of the potential benefits and risks.

4.5 Drug Interactions:

Data evaluating the concomitant administration of Cadiflu-S with other vaccines are not available.

4.6 Use in special population:

Pregnancy:

Animal reproduction studies have not been conducted with Cadiflu-S. However, data from worldwide use of inactivated influenza vaccines do not indicate any adverse foetal and maternal outcomes attributable to the vaccine. Inactivated Flu vaccines can be used in all stages of pregnancy. VLPs are safer vaccine candidates compared to inactivated vaccines.

4.7 Undesirable effects

Safety of Cadiflu-S has been evaluated during Phase-I/II and Phase III clinical studies in 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

Pharmacodynamic properties:

Mechanism of Action:

Influenza viruses have 2 major envelope glycoproteins – haemagglutinin antigen (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 strains, 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 postvaccination (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 prevaccination 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, Influenza A (H1N1) pdm09 like virus; Influenza A (H3N2) like virus and Influenza B (B/Victoria lineage) like virus; were studied in the Phase III trial. Seroprotection rate (≥ 70%) and seroconversion rate (≥ 40%) were achieved for all three strains at day-21 in recipients of the Cadiflu-S vaccine. The criterion of mean fold rise (MFR ≥2.5) was achieved in recipients of the Cadiflu-S vaccine at day-21 post-vaccination for all 3 strains. At day-21 post-vaccination, HAI GMTs were statistically significantly greater in Cadiflu-S vaccine recipients for all 3 strains when compared to placebo arm recipients.

6 PHARMACEUTICALS PARTICULARS

6.1 List of excipients

- Calcium chloride Dihydrate
- Polysorbate 80
- Disodium hydrogen phosphate anhydrous
- Sodium dihydrogen phosphate monohydrate
- Sodium Chloride
- Water for injection

6.2 Incompatibilities:

In the absence of compatibility studies, Cadiflu-S must not be mixed with other medicinal products.

6.3 Shelf life:

12 months when stored at 2-8° C

The expiry date is indicated on the container label.

6.4 Special precautions for storage:

Store at 2-8° C, Do not freeze. Discard if vaccine has been frozen.

6.5 Nature and contents of container:

Pack Size – 0.5 ml, Single dose vial.

Vaccine is filled in USP Type I tubular glass vial (2 ml capacity), stoppered with 13 mm neck diameter rubber stopper and finally sealed with 13mm blue coloured flip off aluminium seal

7 MARKETING AUTHORISATION

Cadila Pharmaceuticals Ltd.

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8. MARKETING AUTHORISATION NUMBER(S)

MF-252/2015

9. DATE OF FIRST AUTHORISATION

17 Dec 2015