

SUMMARY OF PRODUCT CHARACTERISTICS AS PER ANNEXURE C

1. NAME OF THE MEDICINAL PRODUCT

Quadrivalent Influenza Seasonal Vaccine (QIV) (Virus Like Particle)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose 0.5 mL of vaccine contains:	
Active Ingredients	Quantity
A/Wisconsin/588/2019 (H1 N1) pdm 09,	15 mcg
A/Cambodia/e0826360/2020 (H3N2),	15 mcg
B/Washington/02/2019 (B/Victoria lineage),	15 mcg
B/PhukeU3073/2013 (B/Yamagata lineage)	15 mcg
*purified VLP protein produced in Sf9 cells using recombinant Baculovirus Quadrivalent Influenza Seasonal Vaccine (QIV) (Virus Like Particle) contains no egg proteins or antibiotics. Please refer section 7.1 for a full list of excipients.	

3. PHARMACEUTICAL FORM

Quadrivalent Influenza Seasonal Vaccine (QIV) (Virus Like Particle) is a sterile liquid for Intramuscular Injection

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Quadrivalent Influenza Seasonal Vaccine (QIV) (Virus Like Particle) is indicated for active immunization in adults and children older than 6 months of age against disease caused by influenza virus subtypes A and B contained in the vaccine.

4.2 Posology and method of administration

Posology

Adults:

0.5 mL

Paediatric population

Children from 6 months onwards: 0.5 ml. The dose given should be in accordance with the existing national recommendations.

For children aged < 9 years, who have not previously been vaccinated, a second dose should be given after an interval of at least 4 weeks.

Children less than 6 months: the safety and efficacy of Quadrivalent Influenza Seasonal Vaccine (QIV) (Virus Like Particle) in children less than 6 months have not been established. No data are available.

Method of Administration

Quadrivalent Influenza Seasonal Vaccine (QIV) (Virus Like Particle) should be administered as a single 0.5 mL intramuscular injection.

4.3 Contraindications

- Quadrivalent Influenza Seasonal Vaccine (QIV) (Virus Like Particle) is contraindicated in individuals with known severe allergic reactions (e.g. anaphylaxis), to vaccine or any component of the vaccine.
- Immunization shall be postponed in patients with febrile illness or acute infection.

4.4 Special warnings and precautions for use

Limitation of vaccine effectiveness:

Vaccination with Quadrivalent Influenza Seasonal Vaccine (QIV) (Virus Like Particle) may not protect all vaccine recipients.

Preventing and managing allergic reactions:

Prior to administration of Quadrivalent Influenza Seasonal Vaccine (QIV) (Virus Like Particle) the healthcare provider should review the individual's prior immunisation history for possible adverse effects, to determine the existence of any contraindication to immunisation with Quadrivalent Influenza Seasonal Vaccine (QIV) (Virus Like Particle) and 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.

Altered immunocompetence:

If Quadrivalent Influenza Seasonal Vaccine (QIV) (Virus Like Particle) is administered to immunocompromised individuals including persons receiving immunosuppressive therapy, the immune response may be diminished.

4.5 Interaction with other medicinal products and other forms of interaction

There is no data to assess the concomitant administration of Quadrivalent Influenza Seasonal Vaccine (QIV) (Virus Like Particle) with other vaccines.

4.6 Pregnancy and lactation

Pregnancy Category C: Animal reproduction studies have not been conducted with Quadrivalent Influenza Seasonal Vaccine (QIV) (Virus Like Particle). It is also not known whether Quadrivalent

Influenza Seasonal Vaccine (QIV) (Virus Like Particle) can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity.

Lactation: It is not known whether Quadrivalent Influenza Seasonal Vaccine (QIV) (Virus Like Particle) is excreted in human milk. As many drugs are excreted in human milk, caution should be exercised when Quadrivalent Influenza Seasonal Vaccine (QIV) (Virus Like Particle) is administered to a nursing woman.

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 Quadrivalent Influenza Seasonal Vaccine (QIV) (Virus Like Particle).

4.8 Undesirable effects

Safety of Quadrivalent Influenza Seasonal Vaccine (QIV) (Virus Like Particle) has been evaluated in a Phase III clinical study in an Indian population. Quadrivalent Influenza Seasonal Vaccine (QIV) (Virus Like Particle) was found to be safe and well tolerated in the clinical trial. There was no significant difference in adverse event profile between the test and reference arms. The most common adverse events reported were injection site pain and erythema, headache and fever. While incidence of body ache, joint pain, throat irritation and cough were uncommon. Most of the reported AEs were mild in nature.

4.9 Overdose

No data are available on overdose with Quadrivalent Influenza Seasonal Vaccine (QIV) (Virus Like Particle)

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Pharmacotherapeutic group:

Influenza vaccine, ATC Code: J07BB02

Mechanism of action:

Influenza viruses have 2 major glycoproteins – haemagglutinin (HA) and neuraminidase (NA). Protection against clinical disease is mainly conferred by serum antibodies to these glycoproteins. HA is the major antigenic target of virus neutralising antibodies. Antibodies to HA block the attachment of virus to cell surfaces, and is measured by the ability of serum to inhibit 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 A/Brisbane/02/2018 (H1N1); A/Kansas/14/2017 (H3N2); B/Colorado/06/2017 (B/Victoria/2/87 lineage); and B/Phuket/3073/2013 (B/Yamagata lineage).

Immunogenicity:

The immunogenicity endpoints for the Phase III trial (n=660) were evaluated based on HAI antibody titre analysed in blood samples collected at pre-vaccination (day-0) and post-vaccination (day-28) time points. The immunogenicity endpoints included seroprotection rate, seroconversion rate and geometric mean fold rise. Seroprotection was defined as percentage of the subjects achieving an HAI antibody titre ≥ 40 . Seroconversion was defined as percentage of subjects with either pre-vaccination HAI titre < 10 and post-vaccination 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.

Four strains, A/Brisbane/02/2018 (H1N1); A/Kansas/14/2017 (H3N2); B/Colorado/06/2017 (B/Victoria/2/87 lineage); and B/Phuket/3073/2013 (B/Yamagata lineage) were studied in the Phase III trial. The vaccine showed high immunogenicity rates and all the three criteria, i.e., seroconversion in $\geq 40\%$, seroprotection in $\geq 70\%$ and GMR ≥ 2.5 were achieved by all age groups in the trial.

5.2 Pharmacokinetic properties

Not applicable

5.3 Preclinical safety data

Non-clinical data reveals no special hazard for humans based on acute and repeat dose toxicity studies in mice and rats.

6. PHARMACEUTICAL 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

Quadrivalent Influenza Seasonal Vaccine (QIV) (Virus Like Particle) must not be mixed with other medicinal products.

6.3 Shelf life

12 months

6.4 Special precautions for storage

- Store between 2-8°C

- Do not Freeze. Discard if vaccine has been frozen.
- Protect from light
- Shake gently before use

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

Cadila Pharmaceuticals Ltd.

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Dholka-382225

Ahmedabad, Gujarat

8. MARKETING AUTHORISATION NUMBER(S)

MF/BIO/23/000003

9. DATE OF FIRST AUTHORISATION

18 Jan 2023