For use by a Registered Medical Practitioner or Hospital or Laboratory only

Human Inactivated Influenza A (H1N1) 2009 Vaccine

HNVAC™

DESCRIPTION
A Human, inactivated Influenza A (H1N1) 2009 vaccine, **HNVAC**™, is prepared using the pandemic influenza strain A/CALIFORNIA/7/2009 NYMC X-179-A obtained from WHO-accredited Centers for Disease Control and Prevention, USA.

HNVAC™, Inactivated Influenza A (H1N1) 2009 vaccine is a cell culture derived vaccine, produced using Madin-Darby Canine Kidney (MDCK) cells. The virus from cell culture supernatant is harvested, clarified by microfiltration, inactivated and purified by chromatography. The purified virus containing haemagglutinin and neuraminidase antigens are then sterile-filtered.

HNVAC™ is formulated to contain not less than 15 mcg of Haemagglutinin (HA) of Influenza A/CALIFORNIA/7/2009 NYMC X-179-A virus per 0.5 mL dose for intramuscular injection.

COMPOSITION
Each 0.5mL contains:

HA equivalent of Purified, Inactivated Influenza A (H1N1) Virus bulk (Pandemic Strain A/CALIFORNIA/7/2009 NYMC X-179-A)	15 mcg
$Al(OH)_3$ gel as Al^{+++} (Adjuvant)	0.25 mg
Thiomersal I.P. (Preservative)	0.025 mg
Phosphate Buffered Saline	q.s to 0.5 mL

CLINICAL PARTICULARS INDICATION
Influenza A (H1N1) 2009 Vaccine, **HNVAC**™, is an inactivated influenza virus vaccine indicated for active immunization of persons of age 18 years to 65 years against influenza disease caused by pandemic influenza A (H1N1) 2009 virus.

DOSAGE AND ADMINISTRATION
A Single Human Dose is a 0.5 mL intramuscular injection.

CONTRAINDICATIONS
Do not administer the Human Inactivated Influenza A (H1N1) 2009 Vaccine, **HNVAC**™, to anyone with a known history of severe hypersensitivity to any component of the vaccine or life-threatening reactions after previous administration of any influenza vaccine.

MODE OF ADMINISTRATION
Inspect **HNVAC**™ Vaccine vial and Pre-Filled Syringe visually for particulate matter and/or discoloration prior to administration. If either of these conditions exist, the vaccine should not be administered. Shake the pre-filled syringe and vial well before administering the vaccine. A separate syringe and needle or a sterile disposable unit should be used for each injection to prevent transmission of infectious agents from one person to another. Needles or Pre- Filled Syringes used should be disposed of properly and not recapped or reused. **HNVAC**™ should be administered by intramuscular injection only, preferably in the region of the deltoid muscle of the left upper arm. The vaccine should not be injected in the gluteal region or areas where there may be a major nerve trunk. DO NOT inject intravenously or intradermally.

IMMUNIZATION
One single dose of 0.5mL **HNVAC**™ is recommended for immunization of persons 18 years to 65 years of age.

WARNINGS AND PRECAUTIONS
Guillain-Barré Syndrome
If Guillain-Barré syndrome has occurred within 6 weeks of receipt of any prior influenza vaccine, the decision to give **HNVAC**™ should be based on careful consideration of the potential benefits and risks.

Altered Immunocompetence
Immunocompromised patients may have a reduced immune response to **HNVAC**™

Preventing and Managing Allergic Reactions
Prior to administration of **HNVAC**™ Vaccine the healthcare provider should review the patient's prior immunization history for possible adverse events, to determine the existence of any contraindication to immunization with **HNVAC**™ and to allow an assessment of benefits and risks. Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine.

PREGNANCY:
Safety and effectiveness of **HNVAC**™ have not been established in pregnant women and nursing mothers. Therefore this vaccine is not recommended to pregnant or lactating women.

PAEDIATRIC USE:
Safety and effectiveness of **HNVAC**™ have not been established in persons less than 18 years of age; therefore this vaccine is not recommended for use in persons less than 18 years of age.

Limitations of Vaccine Effectiveness

Vaccination with **HNVAC**™ may not protect all individuals.

ADVERSE REACTIONS
Based on adverse event information from clinical trials, some vaccinated subjects develop local pain, redness and swelling. These are mild in nature and last only for 24-48 hours. Small proportion of vaccinees may develop fever which is mild, last for a day or two. The other minor symptoms are itching, allergy, sore-throat, lower limb pain, nausea and malaise.

PHARMACEUTICAL PARTICULARS
Category: Active Immunizing Agent.
Pharmaceutical form: Liquid vaccine for intramuscular injection.

Shelf life : 2 years from date of manufacture.

Store at 2°C to 8°C.

DO NOT FREEZE. DISCARD IF FROZEN.
KEEP OUT OF REACH OF CHILDREN.

PRESENTATION
HNVAC™ is a 0.5mL (Single dose) or 5mL (multi dose) liquid vaccine in a vial.

HNVAC™ PFS is a 0.5mL Pre-Filled Syringe.

Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only

Manufactured & Marketed by

Bharat Biotech
INTERNATIONAL LIMITED
Genome Valley, Shameerpet,
Hyderabad - 500 078. India.

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