Influenza Vaccine (Human, Live Attenuated) (Pandemic (H1N1)) (Freeze-Dried)

DESCRIPTION

Influenza Vaccine (Human, Live Attenuated) Pandemic (H1N1), freeze dried is a live monovalent vaccine for administration by intranasal spray. The influenza vaccine contains influenza virus cultivated on embryonated eggs.

COMPOSITION

[Prophased to Embrionyated hen eggs (SPF)]
Each single dose of 0.5 ml contains:
A/California/07/2009 (H1N1)
Gelatin (Partially hydrolyzed) 2.5%, Sorbitol 5%, L-Alanine 0.1%, L-Histidine 0.21%, Tricine 0.3%, L-Arginine hydrochloride 1.6%
Lactosemonium hydroxide 0.35%, Phosphate buffer saline base.
Reconstitute with Sterile Water for Inhalation USP. The vaccine contains no preservatives.
Dose: 0.5 ml intranasal (spray 0.25 ml per nostril). The tip attached to the sprayer is equipped with a nozzle that produces a fine mist that is primarily deposited in the nose and nasopharynx.

Influenza Vaccine (Human, Live Attenuated) is supplied as a vial containing freeze-dried cake in USP type 1 glass vials. A ampoule vial containing sterile water for inhalation as diluent, syringe (for reconstitution of multi dose vaccine vial), syringe (for administration) needle free device and intranasal spray device are also supplied along with the vaccine. The vaccine complies with the WHO recommendation and EU decision for the pandemic.

INDICATIONS

Influenza Vaccine (Human, Live Attenuated), Intranasal is indicated for the active immunization of individuals above 3 years of age against influenza disease caused by pandemic (H1N1) 2009 virus.

Phylloplas of influenza in an officially declared pandemic situation (see sections Posology and method of administration and Pharmacodynamic properties).

Pandemic influenza vaccine should be used in accordance with official guidance.

POSOLOGY AND METHOD OF ADMINISTRATION

Each freeze-dried vaccine vial is reconstituted using the entire contents of sterile water for Inhalation that is supplied along with the vaccine, using the supplied syringe and valve adapter.

A dose of 0.5 ml is administered as 0.25 ml nostril using a 0.5/1.0 ml syringe and a spray device. The spray device creates a spray that is directed towards the nares and the syringe is also stored in a manner which prevents the proliferation of biofoul. Any open container remaining at the end of session (within six hours of reconstitution) should be discarded.

The vaccine vial monitor (see figure), if present would have been removed on reconstitution.

The diluent supplied is specially designed for use with the vaccine. Only this diluent must be used to reconstitute the vaccine. Do not use diluents from other types of vaccine or from other manufacturers. Using an incorrect diluent may result in damage to the vaccine and/or to serious reactions to those receiving the vaccine. Diluent must not be frozen, but should be kept cool.

The diluent and reconstituted vaccine should be inspected visually for any foreign particulate matter and / or variation of physical aspects prior to administration. In the event of either being observed, discard the diluent or reconstituted vaccine.

CONTRAINDICATIONS

Hypersensitivity

Influenza Vaccine (Human, Live Attenuated) is contraindicated in individuals with a history of hypersensitivity, especially anaphylactic reactions, to eggs, egg proteins, gelatin, or alcohol, or with life-threatening reactions to previous influenza vaccine.

Concomitant Pediatric and Adolescent Aspirin Therapy and Reye's syndrome

Influenza Vaccine (Human, Live Attenuated) is contraindicated in children and adolescents (3-17 years of age) receiving aspirin therapy or aspirin-containing therapy, because of the association of Reye's syndrome with aspirin and wild-type influenza infection.

WARNING AND PRECAUTIONS

Caution is needed when administering this vaccine to persons with a known hypersensitivity (other than anaphylactic reaction) to any of the components, and particularly egg products, egg white, eggs, chicken proteins, etc.

As with all vaccines, appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event following the administration of the vaccine.

Do not administer Influenza Vaccine (Human, Live Attenuated) to children <36 months of age since there is no clinical data available.

Influenza Vaccine (Human, Live Attenuated) should not be administered to any individuals with asthma or children < 5 years of age with recurrent wheezing because of the potential for increased risk of wheezing post vaccination unless the potential benefit outweighs the potential risk.

Do not administer Influenza Vaccine (Human, Live Attenuated) to individuals with severe asthma or active wheezing because these individuals have not been studied in clinical trials.

If Guillain-Barré syndrome has occurred within 6 weeks of prior influenza vaccination, the decision to give influenza Vaccine (Human, Live Attenuated) should be based on consideration of the potential benefits and potential risks. If the pandemic situation allows, immunisation shall be postponed in patients with severe febrile illness or acute infection.

The vaccine can be given to people with minor illnesses (e.g., diarrhea or mild upper respiratory tract infection with or without fever). However, if nasal congestion is present that might limit delivery of the vaccine to the nasal lining, then delaying of vaccination until the nasal congestion is reduced should be considered.

People who are in contact with others with severely compromised immune systems, should not get Influenza Vaccine (Human, Live Attenuated).

Influenza Vaccine (Human, Live Attenuated) should under no circumstances be injected.

Administration of Influenza Vaccine (Human, Live Attenuated), to immunocompromised persons should be based on careful consideration of potential benefits and risks. There is no clinical data available on the use of this vaccine in immunocompromised persons. Antibody response in such patients may be insufficient.

There are no data on co-administration of Influenza Vaccine (Human, Live Attenuated) with other vaccines. However, if co-administration with another vaccine is indicated, immunisation may be carried. It should be noted that the adverse reactions may be intensified.

There are no data regarding co-administration of Influenza Vaccine (Human, Live Attenuated) with other intranasal preparations.

The concurrent use of Influenza Vaccine (Human, Live Attenuated) with antiviral agents that are active against influenza A and B is contraindicated. However, based on the potential benefit for antiviral agents to reduce the effectiveness of Influenza Vaccine (Human, Live Attenuated), do not administer this vaccine until 48 hours after the cessation of antiviral therapy and viral agents should not be administered until two weeks after administration of this vaccine unless medically indicated.

If antiviral agents and Influenza Vaccine (Human, Live Attenuated) are administered concomitantly, reconstitution should be considered when appropriate.

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Drugs Interactions

Do not administer Influenza Vaccine (Human, Live Attenuated) to children or adolescents who are receiving aspirin therapy or aspirin-containing therapy, because of the association of Reye's syndrome with aspirin and wild-type influenza infection.

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The interpretation of the VVM is simple. Focus on the central square. Its colour will change progressively. As long as the colour of the central square is lighter than the outer circle, it is an indication of the cumulative heat to which the vial has been exposed. It warns the end user when exposure to heat is likely to have degraded the vaccine beyond an acceptable level.

The cold (2 to 8ºC) must be maintained when transporting Influenza Vaccine (Human, Live Attenuated) Intra nasal.

The cold (2 to 8°C) must be maintained when transporting Influenza Vaccine (Human, Live Attenuated) Intranasal.

PRESENTATION

Influenza Vaccine (Human, Live Attenuated) Pandemic (H1N1) is available as:
1. dose vial plus diluent (0.5 ml)
5 dose vial plus diluent (2.5 ml).

THE VACCINE VIAL MONITOR (Optional)

Inner square lighter than outer circle. If the expiry date has not passed, USE the vaccine.

At a later time, inner square still lighter than outer circle. If the expiry date has not passed, USE the vaccine.

Discard point: Inner square matches colour of outer circle. DO NOT use the vaccine. Beyond the discard point: Inner square darker than outer ring. DO NOT use the vaccine.

STORAGE

Influenza Vaccine (Human, Live Attenuated) Intranasal SHOULD BE STORED IN A REFRIGERATOR AT 2-8ºC (35-46°F) UPON RECEIPT AND SHOULD NOT BE USED BEFORE THE EXPIRATION DATE ON THE LABEL.

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MOST IMPORTANT WARNING

1. Please ensure that the vaccine is administered by intranasal spray. In rare cases anaphylactic shock may occur in susceptible individual and for such emergency please keep handy 1:1000 adrenaline injection ready to be used either intramuscularly or subcutaneously. For treatment of severe anxiety initial dose of adrenaline is 0.1-0.5 mg (0.1-0.5 ml of 1:1000 injection) given s.c. or i.m. Single dose should not exceed 1 mg (0.1 ml of 1:1000 injection). The recommended dose of adrenaline is 0.015mg/kg (0.015ml/kg of 1:1000 injection). Single paediatric dose should not exceed 0.5 mg (0.5 ml).

2. The mainstay in the treatment of severe anaphylaxis is the prompt use of adrenaline, which can be lifesaving. It should be used at the first suspicion of anaphylaxis. As with the use of all vaccines, the vaccinee should remain under observation for not less than 30 minutes for possibility of occurrence of rapid allergic reaction, anaphylactic shock, angioneurotic oedema and anaphylactoid reactions. Antihistamine should also be available in addition to supportive measures such as oxygen inhalation.

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Protection from birth onwards