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
(Propagated in Embryonated hen eggs (SPF)) Each single dose of 0.5 ml contains:
A/California/2009/2009-like H1N1: 45 HA Units (HI 1:1000)
B/Charles City/2010/2010 (Victoria lineage): 40 HA Units (HI 1:1000)
B/Kharecho/2010/2010 (Yamagata lineage): 40 HA Units (HI 1:1000)

The vaccine contains no preservatives, adjuvants or antibiotics.

A dose of 0.5 ml is administered as 0.25 ml per nostril using a 0.5/1,0 ml syringe and a spray device. The spray device creates a fine spray that primarily deposits the vaccine in the nose and nasopharynx. A single intranasal dose is recommended for people above 3 years of age. If the vaccine is not used immediately then it should be stored at 2-8 ºC for no longer than 6 hours. While storing the reconstituted vaccine, ensure that the administration syringe is locked on to the needle-free transfer device. The combined unit is stored at 2 to 8 ºC to ensure that the opening created by the device is blocked and the syrup is also stored in a manner which prevents the proliferation of bio-burden. Any opened container remaining at the end of a session (within six hours of reconstitution) should be discarded. The vaccine vial may be transferred (see figure) for this type of vaccine is attached to the cap and should be discarded when the vaccine is being reconstituted.

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

PRECAUTIONS
Caution is needed when administering this vaccine to persons with a known hypersensitivity (other than anaphylactic reaction) to the active substance(s), to any of the excipients, and to residues e.g., 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.

CONTRAINDICATIONS
Influenza Vaccine(Human, Live Attenuated) contains influenza virus; therefore, it should not be used in patients who are allergic to eggs, egg protein, or any other component of the vaccine.

The safety of Influenza Vaccine(Human, Live Attenuated) in children has not been established.

M OST IMPORTANT WARNING
1. Please ensure that the vaccine is administered by intranasal spray. In rare cases anaphylactic shock may occur in susceptible individuals and for such emergency please keep handy 1:1000 adrenaline injection ready to be injected intramuscularly or subcutaneously. For treatment of severe anaphylaxis the 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). In children the recommended dose of adrenaline is 0.01 mg/kg (0.01 ml of 1:1000). 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 life-saving. If adrenaline is not available at the first suspicion of anaphylaxis, at the appropriate dose, the vaccinees should remain under observation for not less than 30 minutes for possibility of occurrence of rapid allergic reactions. Hydrocortisone and antihistaminics should also be available in addition to supportive measures such as oxygen inhalation.

3. CAUTION: PEOPLE WHO SHOULD NOT TAKE THE VACCINE
1. Those who are allergic to eggs.
2. Children and adolescents (2-17 years of age) receiving aspirin and aspirin-containing therapy.

Effects on ability to drive and use machines
The vaccine is unlikely to produce an effect on the ability to drive and use machines.

ADVERSE REACTIONS
In clinical trials a few local and systemic reaction were observed. They were mild to moderate in severity and resolved without any sequelae.

Local: Nasal discomfort, stuffy nose, sneezing, runny nose, loss of smell red eyes, lacrimation, facial swelling.

Systemic: Headache, fatigue, myalgia, arthralgia, irritability, loss of appetite, sore throat, cough, diarrhoea.

The incidence of adverse events were noted in both the study groups.

There were a few unsolicited events reported in both the groups and none of them were causally related to study vaccines.

OVERDOSAGE
No case of overdose has been reported.

PHARMACOLOGICAL PROPERTIES
The Western Blot technique may disprove the false positive results and confirm the reactivity of a patient.

Influenza Vaccine(Human, Live Attenuated) is a live monovalent vaccine for administration by intranasal spray. The influenza virus strain in Influenza Vaccine (Human, Live Attenuated) is a cold adapted (ca) (i.e., it replicates efficiently at 32 ºC, that is restrictive for replication of many wild-type influenza viruses); (b) temperature-sensitive (ts) (i.e., it is restricted in replication at 39 ºC, at a temperature at which many wild-type influenza viruses grow efficiently); and (c) attenuated (at) (it does not produce classic influenza-like illness in the ferret model of human influenza infection). The cumulative effect of the antigenic properties and the ca, ts, and att phenotypes is that the attenuated virus replicates in the nasopharynx to induce protective immunity.

Immunomodulatory mechanisms conferring protection against influenza following receipt of Influenza Live Attenuated influenza vaccines are not fully understood, though it is well-established that these vaccines provide clinical protection to the majority of the vaccinated. Likewise, naturally acquired immunity to wild-type influenza has not been completely elucidated. Serum antibodies and mucosal antibodies may play a role in prevention and recovery from infection. However, it is well known that there are no correlations of protection for live influenza vaccines.
PHASE I:  
Reconstitution of the multi-dose vaccine

Retract the plunger of the reconstitution syringe to the half way mark and then install the needle free transfer device.

Remove the flip top of the vial containing the diluent and insert the needle free transfer device with syringe.

Invert the vial and syringe and release the plunger allowing the diluent to flow into the syringe.

Remove the flip top of the vaccine vial.

Insert the needle free transfer device with the attached syringe into the vaccine vial.

Transfer the diluent into the vaccine vial by pushing the plunger of the syringe.

Shake the vial gently and allow it to stand till its contents are fully dissolved.

This completes the reconstitution of the vaccine.

Phase II:  
Administration of the multi-dose reconstituted vaccine

Insert the Administration syringe into the needle free transfer device on the vaccine vial.

Invert the vial and draw vaccine into the syringe up to the 0.25 ml mark.

Open the pack of the intranasal spray device and fix it on the tip of the syringe.

Place the spray device at the base of the nostril of the recipient sitting upright with his head slightly thrown back and push the plunger firmly in a single stroke to deliver the vaccine.

Repeat the above steps so as to draw the second half dose, refill the spray device and administer it into the second nostril of the recipient.

This completes the administration of 1 dose of vaccine to 1 recipient.

Repeat the above procedure using a fresh intranasal spray device for every recipient; but using the same administration syringe for all the remaining doses.

PHASE I:  
Reconstitution of the single dose vaccine

Tap the top of the diluent ampoule for the diluent to drip down. Twist off the top of the ampoule containing the diluent.

Invert the ampoule and syringe and draw out the entire quantity of the diluent into the syringe and remove the empty diluent ampoule.

Fix the Needle Free Transfer Device on the syringe containing the diluent.

Remove the flip top of the vaccine vial.

Shake the vial gently and allow it to stand till its contents are fully dissolved.

This completes the reconstitution of the vaccine.

Insert the needle free transfer device with the attached syringe into the vaccine vial.

Transfer the diluent into the vaccine vial by pushing the plunger of the syringe.

Release the residual vacuum by detaching the syringe and refitting it.

Phase II:  
Administration of the single dose reconstituted vaccine

Invert the vial and draw vaccine into the syringe up to the 0.25 ml mark.

Open the pack of the intranasal spray device and fix it on the tip of the syringe.

Place the spray device at the base of the nostril of the recipient sitting upright with his head slightly thrown back and push the plunger firmly in a single stroke to deliver the vaccine.

Repeat the above steps so as to draw the second half dose, refill the spray device and administer it into the second nostril of the recipient.

This completes the administration of the single dose vaccine to 1 recipient.