PUBLIC ASSESSMENT SUMMARY REPORT– NASOVAC-S

What is Nasovac-S?

Nasovac-S is a live attenuated seasonal influenza vaccine (LAIV) with the following composition:

Lyophilized component:- 1 dose containing not less than 10^7 EID_{50} of live attenuated influenza virus A(H1N1) and A(H3N2) and not less than $10^{6.5}$ EID_{50} of live attenuated influenza virus type B in vial. The strains of A(H1N1), A(H3N2) and Type B will change from time to time to match the strains recommended by WHO for the particular season.

Liquid component (diluent):- 0.5 mL Sterile Water for inhalation for 1 dose

Lyophilized component (Vaccine) is in transparent glass vials and liquid component (Diluent) is in a plastic ampoule

Lyophilized component: White friable mass
Liquid component (diluent): transparent fluid (water)

The entire content of the diluent is used to resuspend the lyophilised component before administration of the vaccine.

VVM type 2

What is Nasovac-S used for?

Nasovac-S is indicated for active immunization against seasonal influenza in individuals ≥2 years of age.

How is Nasovac-S used?

The vaccine is administered intranasally. A dose of 0.5 mL is administered at 0.25 mL per nostril into the 2 nostrils using a 1.0 mL syringe combined with 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 ≥2 years of age.

What are the vaccine characteristics?

Nasovac-S must be stored at 2-8°C. Under these recommended storage conditions, the vaccine is stable for 9 months from the date of last successful potency. Accidental freezing does not affect the vaccine, it is routinely stored at temperatures below -20°C prior to dispatch to the market.

The vaccine does not contain any preservative.

Who is the regulatory authority responsible for its oversight vis a vis WHO?

Nasovac-S was licensed in India, its country of manufacture, by the Central Drugs Standard Control Organization (CDSCO) of India on 03 September 2013.

How has Nasovac-S been studied from the clinical point of view?

Serum Institute of India Ltd (SIIL), as part of the WHO program, manufactured a monovalent H1N1 LAIV vaccine. Safety and immunogenicity was demonstrated in phase I and phase II/III clinical trials, respectively. It was approved for use in persons 3 years of age and over in July 2010 by CDSCO. Further, a case control study demonstrated that vaccine was highly effective in target population. With the same technology, SIIL developed a seasonal trivalent LAIV. Phase I trial in adults demonstrated safety of vaccine with a single dose of 0.5 ml and phase II/III study in persons ≥ 2 years of age with a single dose of 0.5 ml demonstrated immunogenicity of vaccine which was in the line with the reported results of other seasonal live attenuated influenza vaccines. The trivalent vaccine was licensed by the CDSCO in September 2013. In addition a large scale efficacy study demonstrated the clinical efficacy of the seasonal trivalent vaccine in Bangladesh. The original version of the vaccine was developed in Russia and has been in use in Russia for many decades. Several studies have demonstrated efficacy and safety of the original vaccine in Russian pediatric and adult population.

Other information about evaluation of Nasovac-S:

Following appropriate review of the Product Summary File submitted by the manufacturer, evaluation of consistency of final product characteristics and follow-up of implementation of recommendations made by the WHO reviewers, **Nasovac-S** *Influenza vaccine, live attenuated human, seasonal trivalent* has been found acceptable in principle for purchase by United Nations agencies according to the criteria established in the WHO document "Assessing the Programmatic Suitability of Vaccine Candidates for WHO Prequalification" (http://www.who.int/entity/immunization_standards/vaccine_quality/who_pspq_criteria.pdf).

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