FLUAD® (MF59®-Adjuvanted Influenza Vaccine) Fact Sheet

- FLUAD (Influenza Vaccine, Surface Antigen, Inactivated, Adjuvanted with MF59) is *a seasonal influenza vaccine that contains the Novartis proprietary adjuvant MF59*[1]
- *FLUAD has been proven effective in inducing strong immune responses in older adults and young children*[2,3]

The elderly and young children are most at risk for contracting influenza[4]

Due to the weakened or underdeveloped immune systems of older adults and young children, respectively, these groups face the highest risk for contracting seasonal influenza[4,5,6]. These groups are also the most likely to suffer from serious consequences caused by infection, such as worsening chronic conditions, dehydration, hospitalization and even death.

FLUAD was first approved in Europe in 1997 and has been shown to be effective in inducing protective immune responses in older adults and young children[2,3]. The vaccine can also be useful for those with an increased risk of associated complications due to underlying chronic conditions, including diabetes, cardiovascular diseases and respiratory infections[1].

FLUAD is the only MF59-adjuvanted seasonal influenza vaccine. It is indicated for active immunization against influenza in individuals ages 65 and older and is currently licensed in 35 countries* across the European Union, Latin America, Asia Pacific and Canada[1,7]. FLUAD is not licensed for use in children. Submissions for marketing approval of FLUAD in children are ongoing in Canada, Argentina and Brazil.

FLUAD is registered under different brand names by Novartis Vaccines, including Gripguard® in France and Chiromas® in Spain[1].

Study of FLUAD in Older Adults

The Lombardia Influenza Vaccine Effectiveness (LIVE) study was a large-scale, phase III study conducted in Italy during the 2006-7, 2007-8 and 2008-9 influenza seasons to compare the efficacy and safety of FLUAD (MF59-adjuvanted trivalent influenza vaccine, aTIV) to non-adjuvanted trivalent influenza vaccine (TIV)[8,9]. Results found that FLUAD reduced the risk of hospitalizations caused by influenza or pneumonia by 23 percent in older adults compared to the non-adjuvanted vaccine[8,9].

Study of FLUAD in Children

In young children, conventional non-adjuvanted vaccines may only offer 43-59 percent efficacy[3,10].

Phase III data published in *The New England Journal of Medicine* (*NEJM*) showed that FLUAD was highly efficacious in protecting children six months to six years of age against all circulating strains of influenza (86 vs. 43 percent for conventional non-adjuvanted vaccines)[3]. In this study, FLUAD was also well-tolerated and demonstrated a safety profile comparable to conventional non-adjuvanted influenza vaccines in this age group[3].

Safety

FLUAD should not be administered to individuals with known hypersensitivity to any component of FLUAD or to eggs, chicken proteins, kanamycin and neomycin sulfate, formaldehyde, barium sulphate and cetyltrimethylammonium bromide. FLUAD should not be administered to people who have febrile illness or an acute infection[11].

The most common local adverse reactions to FLUAD include injection site pain, redness, swelling, ecchymosis and induration. The most common systemic reactions include fever, malaise, shivering, fatigue, headache, sweating, myalgia and arthralgia[11].

Vaccination with FLUAD may not protect all individuals. Patients with endogenous or iatrogenic immunosuppression or who are undergoing immunosuppressant treatment may have an inadequate response to vaccination[11].

**Argentina, Australia, Austria, Belgium, Bosnia, Brazil, Canada, Chile, Colombia, Croatia, Czech Republic, Denmark, Ecuador, France, Germany, Greece, Hong Kong, Iran, Ireland, Israel, Italy, Luxembourg, Mexico, New Zealand, Philippines, Portugal, Serbia-Montenegro, Singapore, South Africa, South Korea, Spain, Sweden, Switzerland, Thailand, Turkey*

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