VaxigripTetra®

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PROTECTION Beyond Flu

Flu protection for everyone

- **VaxigripTetra® is the only standard-dose influenza vaccine** with data demonstrating proven protection for the broadest range of patients.[1-3]
- You have the power to help protect your patients, aged 6 months and up, against flu with **VaxigripTetra®**.[1]

Flu can wreak havoc across major organ systems

A devastating impact on the body, with complications including heart attack & pneumonia

Neurological

8x increased risk of stroke[6]

Loss of autonomy

23% experience loss of independence[7]

Diabetic complications

75% increased abnormal glycemic events[8]

Cardiovascular

10x increased risk of heart attack[6]

Lower respiratory

8x increased risk of pneumonia*[9]

*in children under age 14

Flu vaccine in Diabetic patients

Influenza vaccination in adults with diabetes can cause *reduction* in hospitalization[10]

Meta analysis: Influenza vaccination in working-age (18–64 years) adults with diabetes†

Influenza vaccination prevented:

All-cause hospitalization
(VE 58%; 95% CI: 6–81%)

Hospitalization due to influenza/pneumonia
(VE 43%; 95% CI, 28–54%)

Influenza vaccination was associated with hospitalization rates reduction for CV outcomes in people with type 2 diabetes[11]

Retrospective cohort analysis of the effectiveness of influenza vaccination in people with type 2 diabetes in England over a 7 year period (N=124,503).

22% ↓ hospitalization for **heart failure**

30% ↓ hospitalization for **stroke**

19% ↓ hospitalization for **acute MI***

World Health Organization

"The **most effective way** to prevent the disease is **vaccination**. Safe and effective vaccines are available and have been used for more than 60 years.

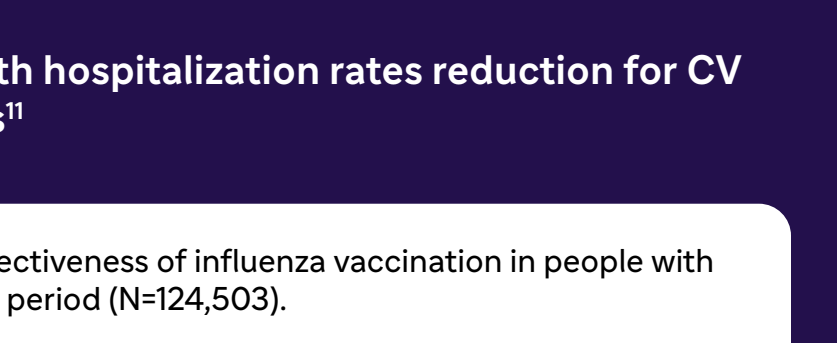
Among healthy adults, influenza vaccine provides protection, even when circulating viruses do not exactly match the vaccine viruses" [12]

VaxigripTetra® is simple and convenient

1 X 0.5 mL dose

- For children more than 6 months of age
- Pregnant women
- Adults

*Vaccination during pregnancy may protect baby from birth to almost 6 months of age.



2 X 0.5 mL doses (with an interval of at least 4 weeks)

- For children less than 9 years old who have not been vaccinated previously

References:

1. Omer SB, Clark DR, Madhi SA,Tapia MD, Nunes MC, et al. Efficacy, duration of protection, birth outcomes, and infant growth associated with influenza vaccination in pregnancy: a pooled analysis of three randomised controlled trials. Lancet Respir Med. 2020;8:597-608, **2.** Pepin S, Samson SI, Alvarez FP, Dupuy M, Gresset-Bourgeois V, De Beuijn I. Impact of a quadrivalent inactivated influenza vaccine on influenza associated complications and health care use in children aged 6 to 35 months: Analysis of data from a phase III trial in the northern and southern hemispheres. Vaccine. 2019;37:1885-1888, **3.** Frobert O, Gotberg M, Erlinge D, et al. Influenza vaccination after myocardial infarction: a randomized double-blind, placebo-controlled, multicenter trial. Circulation. 2021;144(18):1476-1484, **4.** Disease Burden of Influenza (FAQ), **5.** Factsheet about seasonal influenza, **6.** Warren-Gash C, et al. Eur respir J. 2018, **7.** Andrew MK, et al. J Am Geriatr Soc. 2021, **8.** Samson SI, et al. J Diabetes Sci Technol. 2019, **9.** Kubale J et al., Clin Inf Dis. 2021, **10.** RemschmidtC, et al. BMC Med. 2015; 13: 53, **11.** VAMOS EP, ET AL. CAN MED ASSOC J. 2016; 188: E342–51. **12.** WHO, İnfluenza (Seasonal) Available at: https://www.who.int/en/news-room/fact-sheets/detail/influenza-(seasonal).
†Meta analysis of 11 observational studies (N=170,924), *Myocardial infarction, 95% CI, 95% Confidence Interval; NS, not significant; OR, odds ratio; VE, vaccine effectiveness

1-TRADE NAME OF THE MEDICINAL PRODUCT AND PRESENTATION Vaxigrip Tetra, suspension for injection in pre-filled syringe, Quadrivalent influenza vaccine (split virion, inactivated) 2-THERAPEUTIC INDICATIONS Vaxigrip Tetra is indicated for active immunization of adults including pregnant women and children from 6 months of age and older for the prevention of influenza disease caused by the two influenza A virus subtypes and the two influenza B virus types contained in the vaccine. Passive protection of infants from birth to less than 6 months of age following vaccination of pregnant women.3-POSOLOGY AND METHOD OF ADMINISTRATION Based on clinical experience with the trivalent vaccine, annual revaccination with influenza vaccine is recommended given the duration of immunity provided by the vaccine and because circulating strains of influenza virus might change from year to year. Adults: one dose of 0.5 ml. Pediatric population - Children from 6 months to 17 years of age: one dose of 0.5 ml. For children less than 9 years of age who have not previously been vaccinated, a second dose of 0.5 ml should be given after an interval of at least 4 weeks. - Infants less than 6 months of age: the safety and efficacy of Vaxigrip Tetra administration have not been established. No data are available. Regarding passive protection: 0.5 mL dose given to pregnant women may protect infants from birth to less than 6 months of age. METHOD OF ADMINISTRATION: The vaccine should be given by intramuscular or subcutaneous injection. 4-CONTRA-INDICATIONS Hypersensitivity to the active substances, to any of the excipients or to any component that may be present as traces such as eggs (ovalbumin, chicken proteins), neomycin, formaldehyde and octoxinol-9. Vaccination should be postponed in case of moderate or severe febrile disease or acute disease. 5-SPECIAL WARNINGS AND SPECIAL PRECAUTIONS FOR USE As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic reaction following the administration of the vaccine. Vaxigrip Tetra should under no circumstances be administered intravascularly. As with other vaccines administered intramuscularly, the vaccine should be administered with caution to subjects with thrombocytopenia or a bleeding disorder, Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. 6-INTERACTIONS No interaction studies have been performed with Vaxigrip Tetra. 7-PREGNANCY AND LACTATION: Vaxigrip Tetra can be used in all stages of pregnancy. Vaxigrip Tetra may be used during breastfeeding. 8-UNDESIRABLE EFFECTS. Most reactions usually occurred within the first 3 days following vaccination, resolved spontaneously within 1 to 3 days after onset. The most frequently reported adverse reaction after vaccination, in all populations including the whole group of children from 6 to 35 months of age, was injection site pain. In subpopulation of children less than 24 months of age, irritability was the most frequently reported adverse reaction.. In subpopulation children from 24 to 35 months of age, malaise is the most frequently reported adverse reaction. Very common adverse reactions are: headache, myalgia, malaise, shivering, injection site pain, injection site swelling, injection site erythema, injection site induration, For uncommon, rare and very rare side effects see full prescribing information 9-PHARMACODYNAMIC PROPERTIES Pharmacotherapeutic group: Influenza vaccine, ATC code: J07BB02. Date of API: 7 August 2023 based on SMPC NH 2023-2024

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