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FluQuadri™

Vacuna Antiinfluenza Tetravalente de virus fraccionados Tipos A y B

Fórmula 2021

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abla 1: Dosis y esquem	fabla 1: Dosis y esquema para la vacuna FluQuadri	dri
Edad	Dosis	Calendario
De 6 meses a 35 meses	Una o dos dosis ^a , 0,25 mL cada una	Si se aplican 2 dosis, administrarlas por lo menos con un mes de diferencia.
De 36 meses a 8 años	Una o dos dosisª, 0,5 mL cada una	Si se aplican 2 dosis, administrarlas por lo menos con un mes de diferencia.
A partir de 9 años	Una dosis, 0,5 mL	

1 o 2 dosis dependiendo de los antecedentes de vacuna ción y de las recomendaciones locales o nacionales o nacionales que la información no se aplica.

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Special monobolis prelibrada (embol de la jerriga claro), 45 mil. a partir de los 36 mesos de ecidad.

Special monobolis prelibrada (embol de la jerriga claro), 45 mil. a partir de los 36 mesos de ecidad.

ONTANIBATIONE (EMBOL)

La administración de Holden esta contraindicada en caso de pracción allergia gane (por la administración de la ferria de la mode ante centra la influenza.

ONTENTRACIAN Y PRECAUCIONE

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RELACIONES ADVERSAL.

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Ingredientes	Cantidad (Cantidad (por dosis)
	FluQuadri dosis de 0,25 mL	FluQuadri dosis de 0,5 mL
Principio activo: virus de la influenza fraccionados, cepas inactivadas ^a :	30 mcg de HA en total	60 mcg de HA en total
A (H1N1)	7,5 mcg de HA	15 mcg de HA
A (H3N2)	7,5 mcg de HA	15 mcg de HA
B (linaje Victoria)	7,5 mcg de HA	15 mcg de HA

Carrier Bur	mmmm	canada (por dosts)
	FluQuadri dosis de 0,25 mL	FluQuadri dosis de 0,5 mL
ipio activo: virus de la influenza ionados, cepas inactivadas ^a :	30 mcg de HA en total	60 mcg de HA en total
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(H3N2)	7,5 mcg de HA	15 mcg de HA
(linaje Victoria)	7,5 mcg de HA	15 mcg de HA
(linaje Yamagata)	7,5 mcg de HA	15 mcg de HA
lución de cloruro de sodio isotónica nortiguada con fosfato de sodio	CS ^b hasta el volumen apropiado	CS ^b hasta el volumen apropiado
maldehído	≥50 mcg	≤100 mcg
tilfenol etoxilado	≤125 mcg	≤250 mcg
	Mineral	Miles

Conservante

a Seguin for requisitor del Servicio de siluid Mildia de los Estados Unidos (USPHS).

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Vacuna Antiinfluenza Tetravalente de virus fraccionados Tipos A y B Quadrivalent Influenza Vaccine Types A and B subvirion

FluQuadri™

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Elaborado por: Sanofi Pasteur Inc. Swiftwater, PA 18370 EE.UU.

SANOFI PASTEUR 💐

Insert Prints - BLACK Size - Flat: 13-1/2 x 8-1/2; Folded: 3-3/8 x 2-7/8 Package

Spec Part # D000027 / SWT-SPC-007548

Fluzone QIV SEP/CANAC

LE 7708 V1 SEP-CANAC-SyrA 11Dec20

Version 1

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7708

SAP

Part # 794549

100% of actual

size

Flu0uadri™

Quadrivalent Influenza Vaccine **Types A and B subvirion**

2021 Formula

FILL INTEGRATION AND UNDER INTEGRAL INTEGRAL INTEGRAL INTEGRATION AND UNDER CONTROL OF AN INTEGRAL INT

r inframuscura use v.v., e and Schedule e and Schedule for Flu Quadri are presented in Table 1. Table 1: Dose and Schedule for FluQuadri

Schedule	If 2 doses, administer at least 1 month apart	If 2 doses, administer at least 1 month apart	
Dose	One or two doses ^a , 0.25 mL each	One or two doses ^a , 0.5 mL each	One dose, 0.5 mL
Age	6 months through 35 months	36 months through 8 years	9 years and older

 $1\ \text{or}\ 2\ \text{doses}$ depends on vaccination history and local or national recommendations indicates information is not applicable

Admentation Admentation Management and professional prior to administration. Inspect Holload visually for particulate matter and rordisculor prior to administration. If either of these conditions exist, the vaccine should not be administered. Before administering a doze of vaccine, should the prefilled synthesis and memorate and administer of the professional injection are the antercolateral aspect of the thigh in the prefixed is found that though 11 months of age, the arteriolateral aspect of the thigh in other delibid muscle in muscle mass is adequated in persons 12 months through 35 months of age. The active should not be injected into the guideal area or areas where there may be a major rever funds.

Do not administer this product intravenously, intradermally, or subcutaneously. FluQuadri vaccine should not be combined through reconstitution or mixed with any other

DOSAGE FORKE, AND STREKTOR.

Though and a supported for injection.

Though and is supplied in 2 presentations (see Table 1 for Dose and Schedule):

In Petrilet supplied in 2 presentations (see Table 1 for Dose and Schedule):

In Petrilet subsequence overinge (plink syringe plunger and), 0.25 mL, for persons 6 months through 35 months of age.

2.1 Petrilet subsequence syringe (clear syringe plunger rod), 0.5 mL for persons 36 months of age and older.

OUTAMINGTON DATE (8, anabhybis) to any component of the vaccine [see A veere alread reaction (6, anabhybis) to any component of the vaccine is a contradiction to administration of injousiti. WARNINGS AND PRECAUTIONS distriction to administration of injousiti. WARNINGS AND PRECAUTIONS distriction of injousities with the administration of injousities with administration of injousities with administration of injousities and control (16) has been the processor previous influence and instanction of the control benefits and risks are related to the processor of the p

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ADVESE RECTORS

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In childred in central khongy is smonth of aga, the most common (2100) injection-sire reactions were pain (5.700) infection-sire reactions were pain (5.700) of releteness (517.90), exhitren (517.30), and swelling (21.00). In the most common volidical systemic adverse nections were irribative (51.90), and sometime (51.700), paper into (51.200). Invalide (51.800), downwines (51.700), appetite loss (52.300). The common (51.000) inclination with the common (51.000) inclination are neadrins, were pain (56.500, synthem (34.500), and swell with the common (51.000) inclination are neadrins, were pain (56.500, synthem (34.500), and swell of (51.700). The common (51.000) inclination are neadring adverse reactions were impagin (58.500), mallet (61.500), and beached (51.700). Smonths of age

During the 28 days following vaccination, a total of 160,050 recipients in the FluQuadri group, at 160 store requirement in the FluQuadri group, and 160 flow requirement to the FluQuadri group, and 160 flow requirement in the FluQuadri group, 7 (160 glowests in the FluQuadri group of 160 glowests in the FluQuadri group of 160 glowests in the FluQuadri group of the Stickner considered to be possibly traited to vaccination croup in a FluQuadri recipient and 2 group of accident of the FluQuadri recipient and 2 group of accident of the FluXuadri group of accident and a FluXuadri recipient. One death occurred in the TIV1 group of accident relations during the Us, adults 18 years of see and other received one doze in a multi-center trial conducted in the US, adults 18 years of see and other received one doze in a multi-center trial conducted in the US, adults 18 years of see and other received one doze

In a multi-center thal conducted in the US, adults 18 years of age and older received one dose of either fluodand or one of two flormalations compared in themso according either Tor Tur2. Each of the trivalent formulations contained an influenza type 8 bivins in the corresponded to one of the two Yope B bivinse in fluodard is type B vinsus in the illneage or a type B vinsus of the Vanagaal inleage). The softery analysis set included 570 recipients, half aged 18-60 years and half aged 61 years or older.

in additive the sear and defer, the most common (2,24%) injection-size nection was pain (47-4%). The most common solitical systemic adverse reactions were mayalga (22.7%), seadderfor (18.8%) and masket (18.9%) self-mit experience in the following profied, there were two skils, 1 (9.9%) in the following profied, there were two skils, 1 (9.9%) in the following profied, there were two skils, 1 (9.9%) in the following profied, there were two skils, 1 (9.9%) in the following the trial period. Generated Addition, the comparable relationship is a multi-correct instruction of the contrast contrast

Three SAEs were reported during the follow-up period, 2 (0.9%) in the TIV-1 group and 1 (0.4%) in the TIV-2 group, No deaths were reported during the trial period.

Reporting adverse reactions Person and their guardans should be instructed to report any adverse or unusual reaction to their healthcare provider.

Post-Marketing Experience Currently, there are no post-marketing data available for FluQuadri vaccine.

The following events have been spontaneously reported during the post-approval use of the trahert forwards or the use because these events are reported would not always possibly reported during the post-approval use of the trahert forwards or the state because these events are reported would always possible to reliably extend their frequency or appulation of uncertain rise, it is not always possible to reliably entimate their frequency or for each six a capital eligibility and only forwards and their frequency of reporting and trained to state of their consists of eligibility and their sources are observed to their exercise frequency of reporting or strength of eleterect Blood and tymphotic System Disorders. Thermbocytoperia, lymphoderopathy in minute system Disorders callians Barri's yndrome (GRS, convulsions, ferror or school reporting in exercise containing and trained and their post-are consistent or exercise from their strength or post-are containing or exceptioning and trained and section and their sections (including receptioning) and containing the exercision of their receiver their sections of their

- Skin and Subcutaneous Tissue Disorders: Stevens-Johnson syndrome
 - General Disorders and Administration Site Conditions: Pruritus, asthenia/fatigue, pain in extremities, chest pain
 - · Gastrointestinal Disorders: Vomiting

DRUG INTERACTIONS Data evaluating the concomitant administration of FluQuadri with other vaccines are not available.

USE IN SPECIFIC POPULATIONS
Pregament in the production studies have not been conducted with Annual reproduction studies have not been conducted with Fillipsian in the same and the pregament woman or can affect their harm when administered to a pregament woman only if Cash harm when administered to a pregament woman only if Cash harm when administered to a pregnant woman only if Cash hard selected.

It is not known whether EliQuadri is exceed in human milk. Because many drugs are excreed in human milk, caution should be exercised when FuQuadri is administered to a nursing woman.

Pedianic Use

Strip and references of FluQuadri in children below the age of 6 months have not been strip and references as fluQuadri in children below the age of 6 months thought as a faster and removement of the contain was calculated children 6 months thought as a few and in memorarising of FluQuadri was realisted and talk 165 years of age and older (Net A TOTE). And the fluctuation of the containing the

Ingredient	Quantity (per dose)	per dose)
	FluQuadri 0.25 mL Dose	FluQuadri 0.5 mL Dose
Active Substance: Split influenza virus, inactivated strains ^a :	30 mcg HA total	60 mcg HA total
A (H1N1)	7.5 mcg HA	15 mcg HA
A (H3N2)	7.5 mcg HA	15 mcg HA
B/(Victoria lineage)	7.5 mcg HA	15 mcg HA
B/(Yamagata lineage)	7.5 mcg HA	15 mcg HA
Other:		
Sodium phosphate-buffered isotonic sodium chloride solution	QS ^b to appropriate volume	QS ^b to appropriate volume
Formaldehyde	≥50 mcg	≤100 mcg
Octylphenol ethoxylate	≤125 mcg	<250 mcg
Preservative	None	None

a per United States Public Health Service (USPHS) requirement 5 Quantity Sufficient

CLINICAL PREMAKOROGY

MECHANISM of Action

Influenza illessa and its complications follow infection with influenza vinoess. Global influenza illessa and its complications follows influenza incertains. For example, since 1973.

surveillance of influenza identifies yearly antigonic variants. For example, since 1973.

surveillance of influenza identifies yearly antigonic variants. For example, since 1973.

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And the state of the continuous virus type or subtypes order limited or no protection against and the data speaks on a finited awards not an influence virus type or subtype; sometic limited or no protection of a nitred spatial to now an influence that of the earney for the protection described the control of an influence of the control of the subty data singles of entire the virologic basis for second epidemic sand a single in an ingent and the control of the usual change of one or more new state into in each sea, influence ascering the influence a virus calles increaseling the influence as the subtype of the control of the exist calles of the control of the control of the exist calles of the control of the impairment of fertility of the control of the control

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of an a muli-center study conducted in the US, 419 Children & Franchis through 3.5 months in a muli-center study conducted in the Perpendicul of an agent study and start formation and the proportion immunogendicity and advises. Required the Hodudari, Int. 7. or IVE. Ser participants who received two dess. the closes were administed approximately 4 weeks lapari.

Hi antibody geometric mean titers (MI)§ and seroconversion rates 28 days following accordance with Court of the Court of t

Immunogenicity of FluQuadri in Adulte 218 Yeax of Age
In a multicrast study conducted in the US, 555 adults 18 years of age and older who
had received one dose of FluQuadri, TIV-1, or TIV-2 were included in the per-protocol
immunogenicity analysis.

Intellingentied Hall and the Charles and the Hulpandi were non-interior to those following each IVI Chal floor stands are based on respectived criteria file floor filing the Charles and the Charles of the Charles of

The HI antibody GATF following FluQuadri was higher than that following TPC-1 for BiFlorida but not higher than that biflowing TPC for BiFlorida but not higher harbit allowing TPC for BiFlorida but not for the case of the TPC for the CATF [FluQuadri divided by TPC]. It loves finit of the case of the CATF for the CATF for the TPC for the TPC

HOW SUPPLIED/STORAGE AND HANDLING How Supplied Singledcroe, prefiled springe (pink plunger rod), without needle, 0.25 mL, package of 5 (not made with natural rubber lates).

Single-dose, prefilled syringe (clear plunger rod), without needle, 0.5 mL, package of 5 (not made with natural rubber latex).

Storage and Handling Store all Fully added presentations refrigerated at 2° to 8°C (35° to 46°F). DO NOT FREEZE. Store all examples been frozen.

Do not use after the expiration date shown on the label. FluQuadri is a trademark of Sanofi Pasteur Inc.

Manufactured by: Sanofi Pasteur Inc. Swiftwater, PA 18370 USA

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Prints – BLACK Size – Flat: 13-1/2 x 8-1/2; Folded: 3-3/8 x 2-7/8 Package Insert

Spec Part # D000027 / SWT-SPC-007548

SAP Part # 794549

QIV SEP/CANAC

LE 7708 V1 SEP-CANAC-SyrA 11Dec20

높 Version 1

100% of actual size

7708