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Todays Need in Pediatric Practice: Quadrivalent Inactivated Influenza Vaccine-Split Virion

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***Abstract*: Vaccination is the backbone in children's growth year. All types of vaccine should be necessary in pediatric age group. Since last year our country suffering from covid 19 pandemic. As per govt prediction next third wave will be on pediatric age group. So we have to prepare for it, as a part of preparation govt asked to give Influenza vaccine to pediatric age group but there is n number of vaccine available in market. My current article is about quadrivalent inactivated influenza vaccine. *Description*: Quadrivalent Influenza Vaccine for intramuscular injection is an inactivated influenza vaccine, prepared from influenza viruses propagated in embryonated chicken eggs *Ingredients:* A (H1N1), A (H3N2), B/(Victoria lineage), B/(Yamagata lineage) *Indications and usage:* Above 6 months to 65years *Dosage and administration*: 0.25ml/0.5ml (1 or 2 doses 4 weeks apart) *Contraindications:* A severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine. Including egg protein, or to a previous dose of any influenza vaccine is a contraindication to administration. A severe allergic reaction (e.g. anaphylaxis) to any component of the vaccine. Including egg protein, or to a previous dose of any influenza vaccine is a contraindication to administration. *Use in specific populations*: This vaccine should be given to a pregnant woman only if clearly needed. It is not known whether this vaccine is excreted in human milk. Safety and effectiveness of this vaccine in children below the age of 6 months have not been established. Antibody responses to this vaccine are lower in persons more than 65 years of age than in younger adults**

***Keywords*: A(H1N1), A(H3N2), B/(Victoria lineage), B/(Yamagata lineage), hemagglutinins, virologic**

1. Introduction

Vaccination is the backbone in children's growth year. All types of vaccine should be necessary in pediatric age group. Since last year our country suffering from covid 19 pandemic. As per govt prediction next third wave will be on pediatric age group. So we have to prepare for it, as a part of preparation govt asked to give Influenza vaccine to pediatric age group but there is n number of vaccine available in market. My current article is about quadrivalent inactivated influenza vaccine.

2. Description

Quadrivalent Influenza Vaccine for intramuscular injection is an inactivated influenza vaccine, prepared from influenza viruses propagated in embryonated chicken eggs. The virus-containing allantoic fluid is harvested and inactivated with formaldehyde. Influenza virus is concentrated and purified in a linear sucrose density gradient solution using a continuous flow centrifuge. The virus is then chemically disrupted using a non-ionic surfactant, octylphenol ethoxylate, producing a "split virus". The split virus is further purified and then suspended in sodium phosphate-buffered isotonic sodium chloride solution. The process use an additional concentration factor after the ultrafiltration step in order to obtain a higher hemagglutinin (HA) antigen concentration. Antigens from the four strains included in the vaccine are produced separately and then combined to make the quadrivalent formulation.

1) Ingredients

Table 1
Ingredients

Ingredients	**0.25 mL Dose**	**0.5 mL Dose**
Split influenza virus, inactivated strains	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 chloride	6.6 g/L	6.6 g/L
Sodium phosphate dibasic anhydrous	3.830 g/L	3.830 g/L
Sodium phosphate monobasic anhydrous	0.410 g/L	0.410 g/L
Formaldehyde	<50 mcg	<100 mcg
Octylphenol ethoxylate	<125 mcg	<250 mcg

3. Clinical Pharmacology

Mechanism of Action Influenza illness and its complications follow infection with influenza viruses. Global surveillance of influenza identifies yearly antigenic variants. For example, since 1977, antigenic variants of influenza A (H1N1 and H3N2) viruses and influenza B viruses have been in global circulation. Since 2001, two distinct lineages of influenza B (Victoria and Yamagata lineages) have CO-Circulated worldwide. Protection from influenza virus infection has not been correlated with a specific level of hem agglutination inhibition (HI) antibody titer post-vaccination However, in some human studies, antibody titers 21:40 have been associated with protection from influenza illness in up to 50% of subjects. Antibodies against one influenza virus type or subtype confer limited or no antibodies to one antigenic variant of influenza virus might not protect against a new antigenic variant of the same type or subtype.

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Frequent development of antigenic variants through antigenic drift is the virologic basis for seasonal epidemics and the reason for the usual change of one or more new strains in each year's influenza vaccine. Therefore, influenza vaccines are standardized to contain the hemagglutinins of influenza virus strains representing the influenza viruses likely to be circulating in the next season. Annual vaccination with the current vaccine is recommended because immunity during the year after vaccination declines and because circulating strains of influenza virus change from year to year.

1) Indications and usage

It is an inactivated quadrivalent influenza vaccine indicated for the prevention of influenza disease caused by influenza types A and B viruses contained in the vaccine. This vaccine is approved for use in persons 6 months of age and older.

2) Dosage and administration

For intramuscular use only Dose and Schedule

Dose and Schedule: 6 months through 35 months two doses administer at least 4 weeks apart (0.25 ml each dose) Apart 36 months to 8 year two doses, administer at least 4 weeks apart (0.5 mL each dose) 8 years 9 years and older one dose, (0.5 ml)

3) Administration

Inspect the vaccine visually for particulate matter or discoloration prior to administration. If either of these Condition exist, the vaccine should not be administered. Before administering a dose of vaccine, shake the prefilled syringe. The preferred sites for intramuscular injection are the antero-lateral aspect of the thigh In infants 6 months through 11 months of age the antero-lateral aspect of the thigh In persons 12 months through 35 months of age, or the deltoid muscle in persons >36 months of age. The vaccine should not be injected into the gluteal area or areas where there may be a major nerve trunk. Do not administer this product intravenously, intradermal or subcutaneously. This vaccine should not be combined through reconstitution or mixed with any other vaccine.

4) Forms and strengths

It's a suspension for injection. Prefilled single-dose syringe, (0.25 ml) for persons 6 months through 35 months of age. Prefilled single- dose syringe (0.5 mL) for persons 36 months of age and older.

5) Contraindications

A severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine. Including egg protein, or to a previous dose of any influenza vaccine is a contraindication to administration.

6) Warnings and precautions

- Guillain-Barre Syndrome: Recurrence of Guillain-Barre syndrome (GBS) has been temporally associated with administration of influenza vaccine. If GBS has occurred within 6 weeks of previous influenza vaccination, the decision to give vaccine should be based on careful consideration of the potential benefits and risks. Preventing and Managing Allergic Reactions: Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine.
- Altered Immuno competence: If vaccine is administered to immunocompromised persons, including those receiving immunosuppressive therapy, the expected immune response may not be obtained.
- Limitations of Vaccine Effectiveness: This vaccination may not protect all recipients.

7) Adverse reactions

Clinical Trials are conducted under widely varying conditions, adverse event rates observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trial of another vaccine, and may not reflect the rates observed in practice. No deaths were reported during the trial period.

8) Use in specific populations

- *Pregnancy:* Animal reproduction studies have not been conducted with this vaccine, it is also not known whether it can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. This vaccine should be given to a pregnant woman only if clearly needed.
- *Nursing Mothers:* It is not known whether this vaccine is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when vaccine administered to a nursing woman.
- *Pediatric Use:* Safety and effectiveness of this vaccine in children below the age of 6 months have not been established.
- *Geriatric Use:* Safety and immunogenicity of this vaccine was evaluated in adults 65 years of age and older. Antibody responses to this vaccine are lower in persons more than 65 years of age than in younger adults.

9) How supplied/storage and handling

- *Supplied:* (Pediatric) Single-dose, prefilled syringe (0.25 mL) (Adult) Single-dose, prefilled syringe (0.5 mL)
- *Storage and Handling:* Store all vaccines refrigerated at 2° to 8°C (35° to 46°F).
- *Do not freeze*. Discard if vaccine has been frozen. Do not use after the expiry date shown on the vaccine
- *The shelf life:* 12 months.

4. Conclusion

This paper presented an overview of todays need in pediatric practice: quadrivalent inactivated influenza vaccine-split virion

References

[1] Quadrivalent Inactivated Influenza vaccine (Split virion) I.P. NH 2020-2021.