[Description]

The trivalent influenza vaccine (split viorn, inactivated) for intramuscular or deep subcutaneous use, is a sterile suspension containing 2.5 strains of influenza virus propagated in embryonated hen's eggs, concentrated, purified and adsorbed with aluminum hydroxide, trivalent influenza vaccine (split viorn, inactivated) may be contraindicated in individuals with:

- Moderate or severe acute febrile disease.

Allergic reactions:

- Skin reactions that may spread over the body.
- Nerve route pain, numbness and needles sensation,
- Skin reactions that may spread over the body.
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adverse events such as fever, fatigue, weakness and muscle pain is more common in infants and children.

Geriatric use: The trivalent influenza vaccine (split virion, inactivated) is not likely to cause problems or adverse events in the elderly, different from those occurring in young adults, and there are no specific situations limiting the use of the vaccine in elderly patients. After immunization, elderly patients may present lower antibody titers than those obtained in young adults and may therefore remain susceptible to upper respiratory tract infections caused by the influenza virus. However, even if the efficacy of the vaccine may be lower in this group when compared to healthy young adults, elderly patients are highly benefited from vaccination as the vaccine provides high protection against flu-associated complications, frequent in this age group and which are responsible for hospitalizations and deaths.

[Storage]
The trivalent influenza vaccine (split virion, inactivated) should be stored in a refrigerator at +2 °C to +8 °C (35 ° to 46 °F). Do not freeze. Protect from light. Discard product if it has been exposed to freezing. Do not use the vaccine after the expiration date. Keep in its original package. Once opened, the vaccine should be used within 7 days, as long as kept under aseptic conditions and at a temperature of +2 °C to +8 °C (35 ° to 46 °F). As long as maintained under refrigeration, the expiration date for the trivalent influenza vaccine (split virion, inactivated) is 12 months, from the manufacturing date. The expiration date refers to the last day of the month. Keep the vaccine out of children’s reach.

[Presentation]
The trivalent influenza vaccine (split virion, inactivated) is available in packages of 20 x 5 mL (multidose vial - with 10 doses of 0.5 mL). The vials are made of Type I glass. The container closure system for this presentation does not contain latex (natural rubber).

Marketing Authorization Holder:
INSTITUTO BUTANTAN – Av. Dr. Vital Brasil, 1500, Butantã, São Paulo/SP, Brazil.

This leaflet was last approved in 10/18/2021.
The Vaccine Vial Monitors (VVM) are on the cap of trivalent influenza vaccine (split virion, inactivated) supplied by INSTITUTO BUTANTAN. The color dot which appears on the label of the vial is a VVM. This is a time-temperature sensitive dot that provides an indication of the cumulative heat to which the vial has been exposed. It warns the end user when exposure to heat is likely to have degraded the vaccine beyond an acceptable level.

Reading the Vaccine Vial Monitors

The interpretation of the VVM is simple. Focus on the central square. Its colour will change progressively. As long as the colour of this square is lighter than the colour of the circle, then the vaccine can be used. As soon as the colour of the central square is the same colour as the circle or of a darker colour than the circle, then the vial should be discarded.

Gabriel Fioruci Posseti-Desenvolvimento de Embalagens-08/03/2022-09:54:01