Influenza Vaccine (Split Virion), Inactivated
2022/2023 Season,Northern Hemisphere

Common Name: Influenza Vaccine (Split Virion), Inactivated

[Description]
The influenza vaccine (split virion) is a preparation made from the WHO recommended prevalent strains of influenza virus type A and type B which are grown separately in embryonated chicken eggs. After incubation, the virus suspensions in allantoic cavities are harvested. The vaccine is prepared by purification, disruption, re-purification and inactivation of the virus. It is a slightly milky-white liquid.

Active Ingredients: Influenza haemagglutinin derived from each of prevalent influenza virus strain in the year.
A/Victoria/2570/2019 (H1N1)pdm09-like virus.....15μg of haemagglutinin(HA)
A/Darwin/9/2021 (H3N2)-like virus.....15μg of haemagglutinin(HA)
B/Austria/1359417/2021 (B/Victoria lineage)-like virus .....15μg of haemagglutinin(HA)
Each dose of the vaccine should contain 15μg haemagglutinin of each type of flu strain.

Excipients: Sodium dihydrogen phosphate, Sodium hydrogen phosphate,Sodium chloride

Antibiotics contained in the vaccine: gentamicin sulphate.Gentamicin residue shall not be more than 50 ng/dose.

Formaldehyde and Triton X-100 contained in the vaccine: Formaldehyde used for virus inactivation residue shall not be more than 80μg/mL. Triton X-100 residue shall not be more than 150μg/mL.

[Indications]
Susceptible individuals and persons who are liable to be affected by the associated complications. Used in adults and children over 9 years old.

[Action and use]
The product can induce immunity against influenza virus in recipients following immunization. It is used to prevent the infections of the prevalent strains of influenza viruses.

[Specifications]
0.5ml per container. 0.5ml per single human dose used for adults and children over 9 years old shall contain 15μg of influenza haemagglutinin of each influenza virus strain.

[Administration and dosage]
(1)Inject in the deltoid muscle of the lateral upper arm.
(2)Inoculate before and during the epidemic season of influenza. Inject single human dose of 0.5ml vaccine for adults and children over 9 years old.

[Adverse reactions]
Common adverse reactions
(1)Pain, tenderness, redness, swelling and itching may occur at the injection sites generally within 24 hours after vaccination, which can be relieved spontaneously within 2-3 days in most cases.
(2)Transient fever may occur after vaccination and can be relieved spontaneously within a short period and need no particular treatment in most cases.
Rare adverse reactions
(1)Transient common cold symptoms and discomfort may occur after vaccination which can be relieved spontaneously and need no particular treatment.
(2)Severe fever: Physical therapy and symptomatic treatment shall be adopted to prevent febrile convulsion.
Extremely rare adverse reactions
(1)Allergic rash: Urticaria may occur generally within 72 hours after vaccination, if it occurs the recipients shall go to the clinic promptly and receive anti-anaphylactic treatment.
(2)Allergic purpura: The recipients with allergic purpura shall go to the clinic promptly and receive anti-anaphylactic treatment with corticosteroid. If the treatment is inappropriate or delayed, purpuric nephritis may be complicated.
(3)Anaphylactic shock: Anaphylactic shock may occur within one hour after vaccination, emergency measures shall be adopted immediately including prompt injection of adrenaline.

[Contraindications]
(1)Subjects with known allergic reaction to some components of the vaccine, including egg, excipients, formaldehyde, gentamycin sulfate and Triton X-100.
(2)Subjects with acute diseases, severe chronic diseases, and chronic diseases at acute attack stage or cold and fever.
(3)Subjects with uncontrolled epilepsy, other progressive diseases of nervous system or a history of Guillain-Barre syndrome.

[Precautions]
(1)The vaccine shall be administered with caution to the subjects with family or individual history of convulsion and those with chronic diseases, history of epilepsy and allergic diathesis.
(2)Do not use the vaccine if the container shows abnormalities, such as crack, illegible label, exceeding expiry date or turbidity.
(3)The vaccine shall be administered immediately after the container is opened.
(4)Adrenaline should be available for first aid in case of severe anaphylactic reactions. The recipients shall be observed for at least 30 minutes on site following injection.

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(5)The immunization with this vaccine should be deferred for at least one month following administration of immunoglobulin to avoid the influence on immune effect.
(6)Revaccination should be prohibited if any reactions of nervous system would occur after injection.
(7)Freezing is strictly forbidden.

[Use in Pregnancy]
There is no clinical data for use of this vaccine in pregnancy but WHO recommends that influenza vaccine could be administered in pregnant women.

[Storage]
Store and ship the product at 2-8℃, protected from light. Do not freeze

[Packaging]
Vial 1 vial/carton

[Validity period]
12 months

[Drug registration standard]
Executive standard YBS05252018 and conforms with the requirements of Chinese Pharmacopoeia Version 2020（Volume III)

[Product license number]
国药准字S20040058

[Marketing Authorization Holder of Vaccine]/[Manufacturer]
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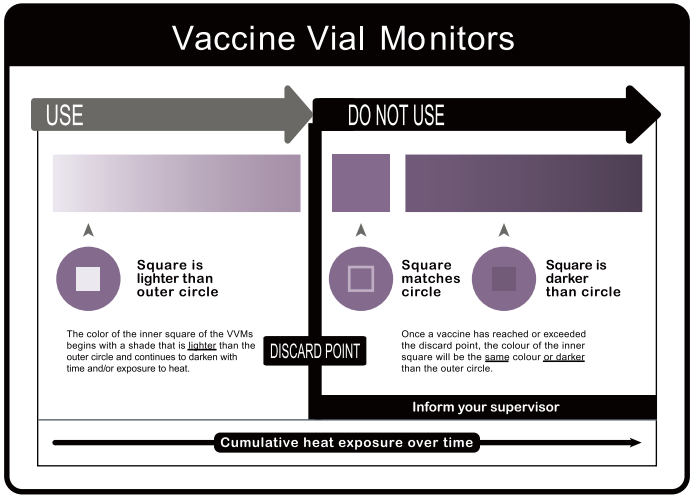
The Vaccine Vial Monitor



The Vaccine Vial Monitor (VVM7) is on the cap of Influenza Vaccine (Split Virion), Inactivated. 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.

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