IMVAMUNE (Monkeypox/Smallpox) Vaccine in Those with Allergic/Immunocompromising Conditions:

Guidance for Allergists/Immunologists from the CSACI

Current as of November 1st, 2022 and based on available evidence to date

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IMVAMUNE is a third generation live-attenuated, non-replicating orthopoxvirus vaccine initially developed for the prevention of smallpox, and recently approved for pre- and post-exposure prophylaxis for monkeypox infections in adults 18 years of age and older.[1] Although not authorized for use among children and youth < 18 years, the National Advisory Committee on Immunization provided a discretionary recommendation for the use of IMVAMUNE in in this group due to possible increased risk of severe infection.[1] IMVAMUNE contains trace amounts of potential drug allergens (tromethamine, gentamicin, ciprofloxacin) and food allergens (egg). In this document, we aim to address the use of IMVAMUNE in populations with possible or confirmed hypersensitivity to these allergens or to the vaccine itself.

Suggested approach to vaccination in individuals with confirmed or suspected allergic reactions to components of the vaccine, or the vaccine itself.

- **Assessment by an allergist is warranted in anyone with suspected anaphylaxis to the IMVAMUNE vaccine.** There is evidence that individuals with immediate allergic reactions to vaccines in general (although less data are available for IMVAMUNE) can safely receive a subsequent dose of the same vaccine with low risk of a systemic reaction under the supervision of an allergist.[2]

- **Assessment by an allergist is not required for those with a confirmed or suspected allergy to vaccine components including antibiotics and/or egg protein.** IMVAMUNE vaccine contains trace amounts of antibiotics (gentamicin and ciprofloxacin) and egg protein. While there is little data specific to IMVAMUNE, extrapolation from other vaccines that contain trace amounts of egg protein demonstrate that individuals with egg allergy, including anaphylaxis to egg, can safely receive these vaccines.[2–4] While tromethamine has been associated with anaphylaxis, the risk of a systemic reaction is extremely low and largely limited to case reports.[5] Similarly, prior data suggest a very low risk of allergic reactions to antibiotics in vaccines. Prolonged observation (30 minutes) may be considered.

- **Assessment by an allergist is not required for those with a confirmed or suspected allergy to tromethamine, including those who have reacted to radiocontrast media. IMVAMUNE** contains trace amounts of tromethamine. The risk of adverse systemic reactions to this compound is extremely low. Millions of individuals are exposed daily to tromethamine in numerous medical and consumer products with no reaction. Prolonged observation (30 minutes) may be considered.

- **Assessment by an allergist is not warranted for any individual who has a history of a mild, localized reaction to a prior dose of the IMVAMUNE vaccine, or to any of its components.** The risk of anaphylaxis is low and these individuals can safely receive a subsequent dose of the same vaccine; a prolonged (30 minute) observation period may be considered.

- **IMVAMUNE is not contraindicated in individuals with atopic dermatitis.** While individuals with atopic dermatitis were at risk of more severe outcomes from prior smallpox vaccines, IMVAMUNE has a favourable safety profile in individuals with atopic dermatitis. Adverse events affecting the skin may be more common but tend to be mild to moderate in intensity.[6]

- **IMVAMUNE may be safely used among individuals who are immunocompromised**, as it is considered a non-replicating vaccine. Studies have been conducted among individuals with HIV with CD4 counts > 100 cells/L and hematopeietic stem cell transplant patients studied 2 years after transplant. Safety was comparable to healthy controls in these two immunocompromised populations.[1]

The literature is likely to evolve over time regarding IMVAMUNE. This statement is reflective of the evidence as it stands to date and will be updated as required.

References

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