Ontario

Ministry of Health

# Vaccine Fact Sheet: Highly Pathogenic Avian Influenza

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This guidance provides basic information only. This document is not intended to provide or take the place of medical advice, diagnosis or treatment, or legal advice.

## Highly Pathogenic Avian Influenza (HPAI)

Avian influenza is a type of influenza A virus mainly found in wild birds. Avian influenza can also infect domestic and commercial poultry, such as chickens and turkeys, and less commonly mammals (including livestock such as dairy cattle), and in rare cases, humans. Avian influenza viruses can be classified as low pathogenic avian influenza (LPAI) or highly pathogenic avian influenza (HPAI) based on the severity of illness in infected poultry.

In recent years, HPAI A(H5N1) has been detected in an unprecedented number of wild and domestic bird and mammalian species worldwide. There have been several reports of human cases of avian influenza A(H5N1) in the United States, primarily among individuals with direct exposures to dairy cattle or poultry. In Canada, a single human case was reported in 2024 with no known source of infection, although the virus subtype matched strains found in wild birds at the time.

Currently, there is no evidence of sustained human-to-human transmission and the overall risk to the general public remains low. However, individuals who are in close, ongoing contact with infected animals or the virus in occupational settings may face a higher risk of exposure.

Ontario continues to monitor for cases of avian influenza and is working collaboratively with health care providers, Public Health Ontario (PHO) and the Public Health Agency of Canada (PHAC) to address health risk(s). This guidance reflects recommendations per the current epidemiology in Ontario and evidence available and will be updated as information evolves.

## The Arepanrix™ H5N1 vaccine

Arepanrix™ H5N1 is a vaccine that has been approved for use by Health Canada as an active immunizing agent against influenza caused by the avian influenza A(H5N1) viruses in adults and children ages 6 months of age and older.

This is a two-component vaccine consisting of inactivated H5N1 virus and an AS03 adjuvant component. This product cannot cause influenza and is not a treatment for avian influenza infection.

## Eligibility for the Arepanrix™ H5N1 vaccine

Based on the current context (i.e., no sustained human-to-human transmission and not in a pandemic state) and the low risk of exposure in Ontario, the following individuals are eligible to receive this vaccine series to protect against human infection with avian influenza A(H5N1), given their ongoing and significant exposure to infected animals and the virus:

- **People with ongoing contact with birds likely to be infected with avian influenza A(H5N1).**
    - Wildlife officers, researchers, rehabilitators who handle dead or sick birds e.g., bird banders)
    - Veterinarians or veterinary technicians who are exposed to dead or sick birds likely infected with avian influenza A(H5N1) (e.g., necropsy).
- **People who handle live avian influenza A(H5N1) virus in laboratory settings.**
    - Examples include laboratory workers who manipulate, handle, or culture live avian influenza A(H5N1) virus such as in research, industrial, or clinical reference laboratory settings.

Other individuals, for example hunters and trappers, may interact with birds or animals that could be infected with avian influenza A(H5N1). However, as these individuals typically interact with live and healthy birds and animals, they are at much lower risk of exposure and are thus not eligible for the vaccine at this time.

Eligible populations may change over time if the context and risk change in Ontario.

Vaccination is voluntary and optional and should be offered to eligible individuals after a risk/benefit discussion with a health care provider that includes a summary of the data available on the vaccine.

## Arepanrix™ H5N1 vaccination schedule

Arepanrix™ H5N1 vaccine is a two-dose vaccine series. The second dose should be given at least three weeks (21 days) after the first dose.

## Coadministration of Arepanrix™ H5N1 vaccine with other vaccines

It is preferable to have an interval of at least 6 weeks between a dose of Arepanrix™ H5N1 vaccine and any other vaccine, including the seasonal influenza vaccine, unless the vaccine is needed urgently. This is a precautionary recommendation to prevent potential misattribution of an adverse event following immunization (AEFI) to the incorrect vaccine.

## Timing of vaccination with Arepanrix™ H5N1 vaccine

Ideal timing for receiving Arepanrix™ H5N1 vaccine series is over the summer of 2025 to provide protection ahead of the fall bird migration season when detections of avian influenza typically increase.

A summer vaccine series would also accommodate the recommended minimum 6 week interval between Arepanrix™ H5N1 vaccine and other vaccines, allowing timely administration of the seasonal influenza vaccine when it becomes available in the fall.

## Arepanrix™ H5N1 vaccine and seasonal influenza vaccination this fall

Eligible individuals who receive the Arepanrix™ H5N1 vaccine are still recommended to receive the seasonal influenza vaccine (flu shot) when they become available this fall.

While it will not provide protection against avian influenza, A(H5N1), the flu shot does reduce the prevalence and severity of infection caused by seasonal influenza. Receiving both vaccines reduces the rare risk of co-infection with both human seasonal influenza and avian influenza viruses. Theoretically, a coinfection carries a risk of a genetic reassortment producing a new influenza virus A, which could pose a significant public health concern.

## Effectiveness of Arepanrix™ H5N1 vaccine

Arepanrix™ H5N1 (A/American wigeon) is the vaccine that will be used in Ontario's publicly funded avian influenza immunization program. There are no direct studies of immunogenicity or effectiveness of this specific vaccine. It was authorized by Health Canada as a strain change to the Arepanrix™ H5N1 (A/Indonesia) product, which was initially approved in 2013 as a pandemic vaccine. This approval process follows the standard practice for strain changes to seasonal influenza vaccines, which do not require clinical trials to support authorization of the annual strain change.

The authorization of the Arepanrix™ H5N1 (A/American wigeon) vaccine was based on clinical data from the Arepanrix™ H5N1 (A/Indonesia) vaccine, which was found to be well tolerated and highly immunogenic against the vaccine strain with some cross-reactivity with other strains.

Based on this available indirect evidence from Arepanrix™ H5N1 (A/Indonesia), as well as other AS03-adjuvanted pandemic vaccines such as Arepanrix™ H1N1 pdm09 and Pandemrix™ H1N1 pdm09 widely used products for pandemic influenza H1N1 in 2009, Arepanrix™ H5N1 (A/American wigeon) is expected to be immunogenic against the currently circulating avian influenza A(H5N1) clade 2.3.4.4b virus.

## Contraindications and precautions for Arepanrix™ H5N1 vaccine

Per the product monograph and Health Canada authorization, Arepanrix™ H5N1 vaccine should not be given to people who have a history of an anaphylactic reaction to any of the constituents or trace residues of the vaccine. Potential allergens include trace egg protein*, Polysorbate 80, and thimerosal.

* Studies have demonstrated that egg-allergic persons can receive influenza vaccines. See Contraindications and precautions chapter of the Canadian Immunization Guide for more information.

## Arepanrix™ H5N1 vaccine and pregnancy

There is currently no data available for use of the Arepanrix™ H5N1 (A/ American wigeon) vaccine and the AS03 adjuvant system for pregnant individuals. However, other AS03-adjuvanted vaccines, Arepanrix™ H1N1 pdm09 and Pandemrix™ H1N1 pdm09, were found to be generally well tolerated with an acceptable safety profile, including in pregnant populations.

Pregnant individuals may consider receiving the vaccine after a risk/benefit discussion with a health care provider, taking into consideration the risks of exposure and potential infection with avian influenza, increased risks of severe disease during pregnancy if infected, the lack of direct data for the Arepanrix™ H5N1 (A/ American wigeon) vaccine, and the indirect safety and vaccine effectiveness data from other similar products.

## Arepanrix™ H5N1 vaccine and breastfeeding

There is currently no data available for use of the Arepanrix™ H5N1 (A/ American wigeon) vaccine and the AS03 adjuvant system for breastfeeding individuals. Breastfeeding individuals may consider receiving the vaccine after a risk/benefit discussion with a health care provider including their risk of exposure to infected animals or the virus.

In general, inactivated vaccines can be safely administered to breastfeeding individuals. For more information, refer to the Immunization in pregnancy and breastfeeding chapter of the Canadian Immunization Guide.

## Arepanrix™ H5N1 vaccine and side effects

Vaccines, like all medications, can have side effects. Rarely, allergic reactions can occur after receiving a vaccine. Immediate medical care should be sought if there are any symptoms of an allergic reaction, including hives, face swelling, tongue or throat, or difficulty breathing following receipt of the Arepanrix™ H5N1 vaccine.

Safety data from clinical trials and indirect evidence suggest that Arepanrix™ H5N1 is generally well tolerated. Most commonly reported side effects were mild to moderate injection site reactions, muscle aches, headache, fatigue, and joint pain.

Any severe, unexpected, or unusual adverse events following the receipt of the Arepanrix™ H5N1 vaccine, whether or not they are clearly attributable to the vaccine, should be reported to the local public health unit.

## Administration of the Arepanrix™ H5N1 vaccine

The Arepanrix™ H5N1 vaccine is administered intramuscularly. Adults 18 years of age and older should receive 2 doses, 0.5 mL per dose. Children and adolescents aged 6 months to 17 years should receive 2 doses, 0.25 mL per dose.

The vaccine consists of two containers: one multidose vial containing the antigen (suspension) and a second multidose vial containing the adjuvant system (emulsion). The product should be stored in a vaccine refrigerator between 2°C to 8°C; it should not be frozen. Prior to mixing, the two components must be brought to room temperature (allow a minimum of 15 minutes). The contents of the adjuvant vial must then be added to the antigen vial and mixed thoroughly by inversion.

Once mixed, the final product (5 mL) contains 10 adult doses (0.5 mL each). The vaccine must be used within **24 hours**. The mixed vaccine can either be stored in the refrigerator (2°C to 8°C) or at room temperature (up to 30°C). If kept in the fridge, it must reach room temperature before each dose is withdrawn. Any unused product should be disposed of after 24 hours from mixing.

Refer to the product monograph for more information, including on storage, handling, and administration of this vaccine.

## More information on avian influenza and Arepanrix™ H5N1 vaccine

For more information on avian influenza or the vaccine, please refer to the resources listed below.

- Government of Ontario: Avian flu
- Public Health Ontario: Avian influenza
- Public Health Agency of Canada: Avian influenza A(H5N1): For health professionals
- National Advisory Committee on Immunization: Preliminary guidance on human vaccination against avian influenza in a non-pandemic context
- Product Monograph: PDF