

## Package leaflet: Information for the user

### Pandemic influenza vaccine H5N1 AstraZeneca, nasal spray suspension

Pandemic influenza vaccine (H5N1)  
(live attenuated, nasal)

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

**Read all of this leaflet carefully before the vaccine is given because it contains important information for you or your child.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- This vaccine has been prescribed for you or your child only. Do not pass it on to others.
- If any of the side effects gets serious, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet:

1. What Pandemic influenza vaccine H5N1 AstraZeneca is and what it is used for
2. What you need to know before you are given Pandemic influenza vaccine H5N1 AstraZeneca
3. How Pandemic influenza vaccine H5N1 AstraZeneca is given
4. Possible side effects
5. How to store Pandemic influenza vaccine H5N1 AstraZeneca
6. Contents of the pack and other information

### 1. What Pandemic influenza vaccine H5N1 AstraZeneca is and what it is used for

Pandemic influenza vaccine H5N1 AstraZeneca is a vaccine to prevent influenza (flu) in an officially declared pandemic. It is used in children and adolescents 12 months to less than 18 years of age.

Pandemic flu is a type of influenza that happens at intervals that vary from less than 10 years to many decades. It spreads rapidly around the world. The signs of pandemic flu are similar to those of ordinary flu but may be more serious.

#### How Pandemic influenza vaccine H5N1 AstraZeneca works

Pandemic influenza vaccine H5N1 AstraZeneca is similar to Fluenz Tetra (a nasal influenza vaccine containing four strains), except Pandemic influenza vaccine H5N1 AstraZeneca provides protection against a single influenza strain in an officially declared pandemic.

When a person is given the vaccine, the immune system (the body's natural defence system) will produce its own protection against the influenza virus. None of the ingredients in the vaccine can cause the flu.

Pandemic influenza vaccine H5N1 AstraZeneca vaccine virus is grown in chicken eggs. The influenza strain used for the vaccine in an officially declared pandemic is recommended by the World Health Organisation.

### 2. What you need to know before you are given Pandemic influenza vaccine H5N1 AstraZeneca

#### You should not be given Pandemic influenza vaccine H5N1 AstraZeneca:

- **if you have previously had a serious allergic reaction (i.e. life-threatening)** to eggs, egg proteins, gentamicin, or gelatin or any of the other ingredients of this vaccine (listed in section 6 "Contents of the pack and other information").

For signs of allergic reactions, see section 4 "Possible side effects". However, in a pandemic situation, your doctor may recommend to give you the vaccine provided that appropriate medical treatment is immediately available in case of an allergic reaction.

If any of these apply, **tell your doctor, nurse or pharmacist.**

#### Warnings and precautions

##### Talk to your doctor, nurse or pharmacist before vaccination:

- if the **child is less than 12 months of age**. Children less than 12 months of age should not receive this vaccine because of the risk of side effects.
- if you have had **any allergic reaction other than a sudden life-threatening allergic reaction** to eggs, egg proteins, gentamicin, or gelatin or any of the other ingredients of this vaccine (listed in section 6 "Contents of the pack and other information").
- if you are **already taking acetylsalicylic acid** (a substance present in many medicines used to relieve pain and lower fever). This is because of the risk of a very rare but serious disease (*Reye's syndrome*).
- if you have a **blood disorder** or a **cancer that affects the immune system**.
- if you have been **told by your doctor** that you have a **weakened immune system** as a result of a disease, medicine, or other treatment.
- if you have **severe asthma** or are currently wheezing.
- if you are in **close contact with someone with a severely weakened immune system** (for example, a bone marrow transplant patient needing isolation).

If any of these apply, **tell your doctor, nurse or pharmacist before vaccination**. He or she will decide if Pandemic influenza vaccine H5N1 AstraZeneca is suitable for you.

### Other medicines, other vaccines and Pandemic influenza vaccine H5N1 AstraZeneca

Tell your doctor, nurse or pharmacist if the person being vaccinated is taking, has recently taken or might take any other medicines, including medicines that do not require a prescription.

- **Do not give acetylsalicylic acid** (a substance present in many medicines used to relieve pain and lower fever) **to children** for 4 weeks after vaccination with Pandemic influenza vaccine H5N1 AstraZeneca unless your doctor, nurse or pharmacist tells you otherwise. This is because of the risk of Reye's syndrome, a very rare but serious disease that can affect the brain and liver.
- **It is recommended that Pandemic influenza vaccine H5N1 AstraZeneca is not given** at the same time as influenza-specific **antiviral medicines** such as *oseltamivir* and *zanamivir*. This is because the vaccine may work less effectively.

Your doctor, nurse or pharmacist will decide if Pandemic influenza vaccine H5N1 AstraZeneca can be given at the same time as other vaccines.

#### Pregnancy and breast-feeding

- If you are **pregnant**, think you may be pregnant, or plan to become pregnant soon, **tell your doctor, nurse or pharmacist before vaccination**. He or she will decide if Pandemic influenza vaccine H5N1 AstraZeneca is suitable for you.
- Pandemic influenza vaccine H5N1 AstraZeneca is **not recommended for breast-feeding** women.

#### Driving and using machines

- Pandemic influenza vaccine H5N1 AstraZeneca has no or negligible influence on the ability to drive and use machines.

### 3. How Pandemic influenza vaccine H5N1 AstraZeneca is given

**Pandemic influenza vaccine H5N1 AstraZeneca will be administered under the supervision of a doctor, nurse or pharmacist.**

Pandemic influenza vaccine H5N1 AstraZeneca must only be used as a nasal spray.

**Pandemic influenza vaccine H5N1 AstraZeneca must not be injected.**

Pandemic influenza vaccine H5N1 AstraZeneca will be given as a spray in each nostril. You can breathe normally while you are given Pandemic influenza vaccine H5N1 AstraZeneca. You do not need to actively inhale or sniff.

#### Dosage

**The recommended dose** for children and adolescents is 0.2 ml Pandemic influenza vaccine H5N1 AstraZeneca, administered as 0.1 ml in each nostril. **All children** will receive a second, follow-up dose after an interval of at least 4 weeks.

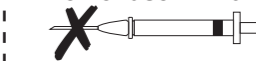
If you have any further questions on this vaccine, ask your doctor, nurse or pharmacist.

## Instructions for healthcare professionals

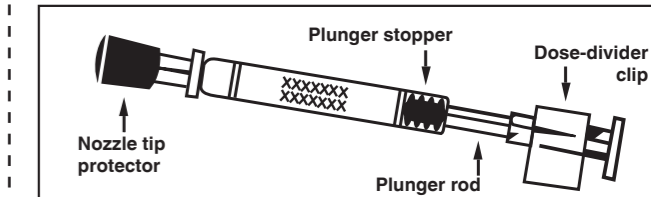
The following information is intended for healthcare professionals only:

**Pandemic influenza vaccine H5N1 AstraZeneca is for nasal use only.**

- **Do not use with a needle.** Do not inject.

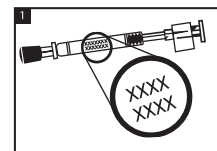


- Do not use Pandemic influenza vaccine H5N1 AstraZeneca if the expiry date has passed or the sprayer appears damaged, for example, if the plunger is loose or displaced from the sprayer or if there are any signs of leakage.
- Pandemic influenza vaccine H5N1 AstraZeneca is administered as a divided dose in both nostrils as described below. (See also *How Pandemic influenza vaccine H5N1 AstraZeneca is given*, in section 3).
- After administering half of the dose in one nostril, administer the other half of the dose in the other nostril immediately or shortly thereafter.
- The patient can breathe normally while the vaccine is being administered – there is no need to actively inhale or sniff.



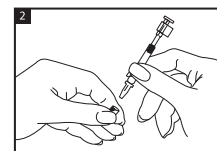
#### Check expiry date

Product must be used before date on applicator label.



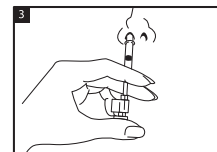
#### Prepare the applicator

Remove rubber tip protector. Do not remove dose-divider clip at the other end of the applicator.



#### Position the applicator

With the patient in an upright position, place the tip just inside the nostril to ensure Pandemic influenza vaccine H5N1 AstraZeneca is delivered into the nose.



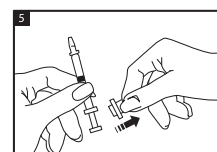
#### Depress the plunger

With a single motion, depress plunger **as rapidly as possible** until the dose-divider clip prevents you from going further.



#### Remove dose-divider clip

For administration in the other nostril, pinch and remove the dose-divider clip from plunger.



#### Spray in other nostril

Place the tip just **inside the other nostril** and with a single motion, depress plunger **as rapidly as possible** to deliver remaining vaccine.



See section 5 for advice on storage and disposal.

#### 4. Possible side effects

Like all medicines, this vaccine can cause side effects, although not everybody gets them. In clinical studies with the vaccine, most side effects were mild in nature and short-term.

Ask your doctor, nurse or pharmacist if you want more information about possible side effects from Pandemic influenza vaccine H5N1 AstraZeneca.

##### Some side effects may be serious:

###### Very rare

(may affect up to 1 in 1,000,000 people):

- severe allergic reaction: signs of a severe allergic reaction may include shortness of breath and swelling of the face or tongue.

**Tell your doctor straightaway or seek urgent medical care** if you experience any of the effects above.

In clinical studies with adults who received Pandemic influenza vaccine H5N1 AstraZeneca, the most common side effects were headache and upper respiratory tract infection (inflammation of the nose, throat and sinuses).

##### Other possible side effects of Pandemic influenza vaccine H5N1 AstraZeneca:

###### Very common

(may affect more than 1 in 10 people):

- runny or stuffy nose
- reduced appetite
- weakness

###### Common

(may affect up to 1 in 10 people):

- fever
- muscle aches

#### Uncommon

(may affect up to 1 in 100 people):

- rash
- nose bleed
- allergic reactions

#### Reporting of side effects

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

#### Ireland

HPRA Pharmacovigilance  
Website: [www.hpra.ie](http://www.hpra.ie)

#### Malta

ADR Reporting  
Website: [www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal)

#### 5. How to store Pandemic influenza vaccine H5N1 AstraZeneca

Keep this vaccine out of the sight and reach of children.

Do not use this vaccine after the expiry date which is stated on the applicator label after the letters EXP.

Store in a refrigerator (2°C to 8°C). Do not freeze.

Keep the nasal applicator in the outer carton in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

#### 6. Contents of the pack and other information

##### What Pandemic influenza vaccine H5N1 AstraZeneca contains

The active substance is:

Reassortant influenza virus\* (live attenuated) of the following strain\*\*:

A/Vietnam/1203/2004 (H5N1) strain (A/Vietnam/1203/2004, MEDI 0141000136)  $10^{7.0\pm 0.5}$  FFU\*\*\* per 0.2 ml dose

\* propagated in fertilised hens' eggs from healthy chicken flocks.

\*\* produced in VERO cells by reverse genetic technology. This product contains a genetically modified organism (GMO).

\*\*\* fluorescent focus units

This vaccine complies with the WHO recommendation and EU decision for the pandemic.

The other ingredients are sucrose, dipotassium phosphate, potassium dihydrogen phosphate, gelatin (porcine, Type A), arginine hydrochloride, monosodium glutamate monohydrate and water for injections.

##### What Pandemic influenza vaccine H5N1 AstraZeneca looks like and contents of the pack

This vaccine is presented as a nasal spray suspension in a single-use nasal applicator (0.2 ml) in a pack size of 10.

The suspension is colourless to pale yellow, clear to slightly cloudy. Small white particles may be present.

#### Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:	Manufacturer:
AstraZeneca AB	MedImmune Pharma B.V.,
SE-151 85	Lagelandseweg 78
Södertälje	Nijmegen, 6545CG
Sweden	Netherlands

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

#### Ireland

AstraZeneca Pharmaceuticals (Ireland) Ltd  
Tel: +353 1609 7100

#### Malta

Associated Drug Co. Ltd  
Tel: +356 2277 8000

#### This leaflet was last revised in 03/2019.

This medicine has been given "conditional approval". This means that there is more evidence to come about this medicine. The European Medicines Agency will review new information on this medicines at least every year and this leaflet will be updated as necessary.

#### Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:  
<http://www.ema.europa.eu>