1. What Pandemic influenza vaccine H5N1 AstraZeneca is and is what it is 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 10 years of age.

Flu vaccine is a type of flu vaccine that happens at intervals that vary from less than 10 years to many decades. It appears 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 (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 flu.

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

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 severe allergic reaction (e.g. life-threatening reactions) to egg, egg proteins, 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 the 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, 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) or children less than 12 months of age. Children less than 12 months of age should not receive the vaccine because of the risk of side effects.

- If you are already taking acetylsalicylic acid (a substance present in many medicines used to relieve pain and lower fever). This is because the vaccine may work less effectively.

- 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, cancer, or treatment.

- If you have had asthma or are currently wheezing.

- If you are in close contact with someone with a recently 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 canamivir and oseltamivir. 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 breastfeeding

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 breastfeeding 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 breathe normally while you are given Pandemic influenza vaccine H5N1 AstraZeneca. You do not need to actively inhale or sniff.

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.

Pandemic influenza vaccine H5N1 AstraZeneca:

- is given as two doses in the nostrils, with the second dose given in the other nostril.
- is given as two doses in the nostrils, with the second dose given in the first nostril.

4. Possible side effects

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

In instructions for healthcare professionals

The following information is intended for healthcare professionals 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 vial appears damaged, for example, if the plunger is loose or displaced from the vial 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.
2. Possible side effects

### Possible side effects

- Use 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 100,000 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:**
  - nausea
  - 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.

### How to store Pandemic influenza vaccine H5N1 AstraZeneca

- Keep this vaccine out of the sight and reach of children.
- Store in a refrigerator (2°C to 8°C). Do not freeze.
- Do not use this vaccine after the expiry date which is stated on the applicator label after the letters EXP.
- Keep this vaccine in the outer carton in order to protect it 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.

### 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 strains:


- produced in VERO cells by reverse genetic technology.
- This product contains a genetically modified organism (GMO).
- This vaccine complies with the WHO recommendation and EU decision for the pandemic.
- The component ingredients are sucrose, dextrose, phosphate, potassium dihydrogen phosphate, gelatin (porcine, Type A), arginine hydrosulphate, monosodium glycolate monohydrate and water for injection.

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.

### How to use Pandemic influenza vaccine H5N1 AstraZeneca

- Place the tip just inside the nostril and with a single motion, depress the plunger as rapidly as possible and with a single motion, depress plunger
  - Spray in other nostril
  - Pinch and remove the dose-divider clip

### For administration in the other nostril

- Remove dose-divider clip
- The dose-divider clip prevents you from going further.
- As you hold the nasal applicator firmly, spray in the nostril:
  - (may affect up to 1 in 10 people):
    - weakness
    - reduced appetite
    - nose bleed
    - muscle aches
  - (may affect up to 1 in 50 people):
    - fever
    - runny or stuffy nose
    - reduced appetite
    - nose bleed
    - muscle aches
  - (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.

### How to store Pandemic influenza vaccine H5N1 AstraZeneca

- Keep this vaccine out of the sight and reach of children.
- Store in a refrigerator (2°C to 8°C). Do not freeze.
- Do not use this vaccine after the expiry date which is stated on the applicator label after the letters EXP.
- Keep this vaccine in the outer carton in order to protect it 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.

### 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 strains:

A/Vietnam/1203/2004 (H5N1) strain (A/Vietnam/1203/2004,
MEDC 014/2001/1036) **

- produced in VERO cells by reverse genetic technology.
- This product contains a genetically modified organism (GMO).
- This vaccine complies with the WHO recommendation and EU decision for the pandemic.
- The component ingredients are sucrose, dextrose, phosphate, potassium dihydrogen phosphate, gelatin (porcine, Type A), arginine hydrosulphate, monosodium glycolate monohydrate and water for injection.

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.

### How to use Pandemic influenza vaccine H5N1 AstraZeneca

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

### See section 5 for advice on storage and disposal.