Uncommon (affects 1 to 10 users in 1,000):
- generalised skin reactions including urticaria (hives)

Rare (affects 1 to 10 users in 10,000):
- allergic reactions leading to a dangerous decrease of blood pressure, which, if untreated, may lead to shock. Doctors are aware of this possibility and have emergency treatment available for use in such cases.
- severe stabbing or throbbing pain along one or more nerves
- low blood platelet count which can result in bleeding or bruising

Very rare (affects less than 1 user in 10,000):
- vasculitis (inflammation of blood vessels which can cause skin rashes, joint pain and kidney problems)
- neurological disorders such as encephalomyelitis (inflammation of the central nervous system), neuritis (inflammation of nerves) and a type of paralysis known as Guillain-Barré Syndrome

Reporting of side effects
If you get any side effects talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store VEPACEL

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

Do not use this medicine after the expiry date which is stated on the carton and the label. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C - 8°C).
Store in the original package in order to protect from light.
Do not freeze.

After first opening, the vaccine should be used immediately (within a maximum period of 3 hours).

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 to protect the environment.

6. Contents of the pack and other information

What VEPACEL contains

- The active substance is:
  1 dose (0.5 ml) contains:
  Influenza virus (whole virion, inactivated), containing antigen of*strain:
  A/Vietnam/1203/2004 (H5N1) 7.5 micrograms**
  * produced in Vero cells
  ** haemagglutinin

- The other ingredients are
  Trometamol
  Sodium chloride
  Water for injections
  Polysorbate 80.

What VEPACEL looks like and contents of the pack

VEPACEL is presented as a suspension for injection in multidose vial (10 doses of 0.5 ml per vial) in pack size of 20 vials.

The suspension is clear to opalescent.

Marketing Authorisation Holder

Ology Bioservices Ireland LTD
Wilton Park House
Wilton Place
Dublin 2
D02P447
Ireland

Manufacturer

Baxter AG
Uferstrasse 15
A-2304 Orth/Donau
Austria

This leaflet was last revised in

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

The following information is intended for healthcare professionals only:

Multidose vial (10 doses of 0.5 ml per vial)

The vaccine should be allowed to reach room temperature before use. Shake before use.

After shaking, the vaccine is a clear to opalescent suspension.
Prior to administration, visually inspect the suspension for any foreign particulate matter and/or abnormal physical appearance. In the event of either being observed, discard the vaccine.

The vaccine should not be administered intravascularly.

Any unused vaccine or waste material should be disposed of in accordance with local requirements.

After first opening, the vial is to be used within a maximum of 3 hours.

Each vaccine dose of 0.5 ml is withdrawn into a syringe for injection.

Package leaflet: Information for the user
VEPACEL suspension for injection
Prepandemic influenza vaccine (H5N1) (whole virion, inactivated, prepared in cell culture)

▼ 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 you receive this vaccine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any of the side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What VEPACEL is and what it is used for

VEPACEL is a vaccine for use in individuals aged 6 months and older. It is intended to be given before the next influenza (flu) pandemic to prevent flu caused by the H5N1 type of the virus.

Pandemic flu is a type of influenza that occurs every few decades and which spreads rapidly around the world. The symptoms of pandemic flu are similar to those of an ordinary flu but are usually more severe.

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

As with all vaccines, VEPACEL may not fully protect all persons who are vaccinated.

2. What you need to know before you receive VEPACEL

You should not receive VEPACEL

- if you have previously had a severe allergic reaction to any ingredient of VEPACEL (these are listed at the end of the leaflet – section 6) or to any substances that may be present in trace (very low) amounts: formaldehyde, benzonase, sucrose, trypsin, Vero host cell protein.
  Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue. However, in a pandemic situation, it may be appropriate for you to have the vaccine, provided that appropriate medical treatment is immediately available in case of an allergic reaction.

If you are not sure, talk to your doctor or nurse before having this vaccine.

Warnings and precautions

You should tell your doctor before vaccination:
- if you have a severe infection with a high temperature (over 38°C). If this applies to you then your vaccination will usually be postponed until you are feeling better. A minor infection such as a cold should not be problem, but your doctor should advise whether you could still be vaccinated with VEPACEL.
- if you have had any allergic reaction to any ingredient of the vaccine (see section 6 at the end of the leaflet) or trace residues (formaldehyde, benzonase, sucrose, trypsin, Vero host cell protein). Allergic reactions, including sudden life-threatening allergic reactions (anaphylaxis) have been reported following use of a similar vaccine for H1N1 influenza during a pandemic period. Such reactions have occurred both in patients with a history of multiple allergies and in patients with no known allergy.
- if you have a weakened immune system as for example because of immunosuppressive therapy, e.g. taking of corticosteroids or treatment for cancer.
- if you have a bleeding problem or bruise easily.

If you need a blood test to look for evidence of infection with certain viruses in the first few weeks after vaccination with VEPACEL, the result of the test may not be correct. Tell the doctor requesting the test that you have recently received VEPACEL.

The vaccine should never be given into a blood vessel.
There is no information on the use of VEPACEL under the skin.

In any of these cases, TELL YOUR DOCTOR OR NURSE, as vaccination may not be recommended, or may need to be delayed.

Other medicines and VEPACEL

Please tell your doctor or nurse if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, or if you have recently received any other vaccine.

There is no information on administration of VEPACEL with other vaccines. However, if this cannot be avoided, the other vaccine should not be injected into the same arm used for VEPACEL.
You should be aware that side effects may be intensified.

If you take any medicines that reduce immunity to infections or have any other type of treatment that affects the immune system (such as radiotherapy), VEPACEL can still be given but your response to the vaccine may be poor.

VEPACEL should not be given at the same time as immunoglobulins. However, if this cannot be avoided, the immunoglobulins should not be injected into the same arm used for VEPACEL.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor for advice if you should receive VEPACEL.

Driving and using machines

VEPACEL may affect your ability to drive and use machines.

3. How VEPACEL is given

Your doctor or nurse will administer the vaccine in accordance with official recommendations. The vaccine will be injected into the muscle of the upper arm (deltoid muscle) or upper thigh, depending on the muscle mass. The vaccine should never be given into a vein.

Infants, children and adolescents from the age of 6 months to 17 years and adults from the age of 18 years:
One dose of 0.5 ml will be given. A second dose of 0.5 ml should be given after an interval of at least three weeks.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

In the clinical studies conducted in adults and older people most side effects were mild in nature and short term. The side effects are generally similar to those related to the flu vaccine. There were fewer side effects after the second vaccination compared with the first. The most frequently occurring side effect was injection- site pain, which was usually mild.

The following side effects have been reported in clinical studies in adults and older people

Very common (affects more than 1 user in 10):
- pain at the injection site
- fatigue (feeling tired)
- headache

Common (affects 1 to 10 users in 100):
- runny nose and sore throat
- vertigo (a spinning sensation)
- pain in mouth and throat
- cough
- diarrhoea
- increased sweating
- itching
- pain in joint or muscle
- fever
- chills
- malaise (generally feeling unwell)
- hardness, redness, swelling or bruising at the injection site
- abnormal, reduced sensation

Uncommon (affects 1 to 10 users in 1,000):
- swollen glands
- insomnia (difficulty sleeping)
- dizziness
- sleepiness
- conjunctivitis (an inflammation of the eye), eye irritation
- ear pain
- reduced blood pressure, feeling faint (syncope)
- shortness of breath
- stuffy nose
- dry throat
- vomiting

- feeling sick
- stomach pain, upset stomach
- rash, hives
- chest discomfort
- flu-like illness
- injection-site reaction such as irritation, itching, bruising or stiff arm
- sudden hearing loss

In the clinical studies conducted in infants, children and adolescents, the incidence and nature of symptoms after the first and second vaccination were similar to those occurred in adults or older people.

a) The following side effects have been reported in a clinical study in infants aged 6 to 35 months.

Very common (affects more than 1 user in 10):
- sleepiness
- pain at the injection site
- fever
- irritability

Common (affects 1 to 10 users in 100):
- runny nose and sore throat
- decreased appetite
- sleep disorder
- crying
- feeling sick
- vomiting
- diarrhoea
- increased sweating
- hardness, redness, swelling or bruising at the injection site

b) The following side effects have been reported in clinical studies in children aged 3 to 8 years.

Very common (affects more than 1 user in 10):
- pain at the injection site

Common (affects 1 to 10 users in 100):
- runny nose and sore throat
- headache
- pain in mouth and throat
- feeling sick
- vomiting
- pain in joint or muscle
- hardness, redness, swelling or bruising at the injection site
- fever
- malaise
- fatigue (feeling tired)

Uncommon (affects 1 to 10 users in 1,000):
- decreased appetite
- eye irritation
- cough
- runny nose
- diarrhoea
- increased sweating

- itching where the injection was given
- pain in the armpit
- feeling cold

c) The following side effects have been reported in clinical studies in adolescents aged 9 to 17 years.

Very common (affects more than 1 user in 10):
- headache
- pain at the injection site

Common (affects 1 to 10 users in 100):
- runny nose and sore throat
- pain in mouth and throat
- stomach pain
- feeling sick
- vomiting
- increased sweating
- pain in joint or muscle
- hardness, redness or swelling at the injection site
- fatigue (feeling tired)
- chills
- malaise

Uncommon (affects 1 to 10 users in 1,000):
- decreased appetite
- insomnia (difficulty sleeping)
- dizziness
- abnormal, reduced sensation
- vertigo (a spinning sensation)
- cough
- runny nose
- diarrhoea
- itching
- pain in extremity
- bruising at the injection site
- itching where the injection was given
- pain in the armpit
- fever
- feeling cold

There are no post-marketing data available for VEPACEL.

Side effects observed with a similar influenza vaccine (Celvapan)
The side effects listed below have occurred with a similar influenza vaccine (Celvapan) in adults and children during the H1N1 pandemic flu vaccination programme:
- allergic reactions, including anaphylactic reactions leading to a dangerous decrease in blood pressure which, if untreated, may lead to shock
- fits due to fever
- pain in arms and/or legs (in the majority of cases reported as pain in the vaccination arm)
- swelling of tissue just below the skin

Side effects observed with flu vaccines given routinely every year
In the days or weeks after vaccination with vaccines given routinely every year to prevent flu, the side effects listed below have occurred. These side effects may occur with VEPACEL.

Uncommon (affects 1 to 10 users in 1,000):
- generalised skin reactions including urticaria (hives)

Rare (affects 1 to 10 users in 10,000):
- allergic reactions leading to a dangerous decrease of blood pressure, which, if untreated, may lead to shock. Doctors are aware of this possibility and have emergency treatment available for use in such cases.
- severe stabbing or throbbing pain along one or more nerves
- low blood platelet count which can result in bleeding or bruising

Very rare (affects less than 1 user in 10,000):
- vasculitis (inflammation of blood vessels which can cause skin rashes, joint pain and kidney problems)
- neurological disorders such as encephalomyelitis (inflammation of the central nervous system), neuritis (inflammation of nerves) and a type of paralysis known as Guillain-Barré Syndrome

Reporting of side effects
If you get any side effects talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store VEPACEL

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

Do not use this medicine after the expiry date which is stated on the carton and the label. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C - 8°C).
Store in the original package in order to protect from light.
Do not freeze.

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 to protect the environment.

6. Contents of the pack and other information

What VEPACEL contains

- The active substance is:
  One dose (0.5 ml) contains:
  Influenza virus (whole virion, inactivated), containing antigen of*strain :
  A/Vietnam/1203/2004 (H5N1) 7.5 micrograms**
  * produced in Vero cells
  ** haemagglutinin

- The other ingredients are
  Trometamol
  Sodium chloride
  Water for injections
  Polysorbate 80.

What VEPACEL looks like and contents of the pack

VEPACEL is presented as a suspension for injection in a pre-filled syringe.

1 pack of a pre-filled syringe containing a single dose of 0.5 ml suspension for injection with a latex-free plunger (halogeno-butyl-rubber) without needles.

The suspension is clear to opalescent.

Marketing Authorisation Holder

Ology Bioservices Ireland LTD
Wilton Park House
Wilton Place
Dublin 2
D02P447
Ireland

Manufacturer

Baxter AG
Uferstrasse 15
A-2304 Orth/Donau
Austria

This leaflet was last revised in May 2015

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

The following information is intended for healthcare professionals only:

The vaccine should be allowed to reach room temperature before use. Shake before use.

After shaking, the vaccine is a clear to opalescent suspension.

Prior to administration, visually inspect the suspension for any foreign particulate matter and/or abnormal physical appearance. In the event of either being observed, discard the vaccine.

The vaccine should not be administered intravascularly.

Any unused vaccine or waste material should be disposed of in accordance with local requirements.

After removing the syringe cap, attach the needle immediately and remove the needle shield prior to administration.

Once the needle is attached, the vaccine must be administered immediately.