

Consumer Medicine Information

CELVAPAN

Pandemic Influenza Vaccine (H1N1) (whole virion, Vero cell derived, inactivated)suspension for injection

Read all of this leaflet carefully before you receive this vaccine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

What is in this leaflet

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2. Before you receive CELVAPAN
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What CELVAPAN is and what it is used for

CELVAPAN is a vaccine to prevent influenza (flu).

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 may be more severe.

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

Before you receive CELVAPAN

You should not receive CELVAPAN

- If you previously had a sudden life-threatening allergic reaction to any ingredient of CELVAPAN or to any of the substances that may

be present in trace amounts as follows: formaldehyde, benzonase, sucrose.

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.

Take special care with CELVAPAN:

- if you have had any allergic reaction other than a sudden life-threatening allergic reaction to any ingredient contained in the vaccine, to formaldehyde, benzonase, or to sucrose (see Further information).
- 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 a problem, but your doctor or nurse should advise whether you could still be vaccinated with CELVAPAN.
- if you are having a blood test to look for evidence of infection with certain viruses. In the first few weeks after vaccination with CELVAPAN the results of these tests may not be correct. Tell the doctor requesting these tests that you have recently been given CELVAPAN,

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

Please inform your doctor or nurse if you have a bleeding problem or bruise easily.

Allergic reactions (including anaphylaxis) have been reported following vaccination with CELVAPAN (see Possible Side Effects).

Taking other medicines

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

There is no information on administration of the vaccine CELVAPAN with other vaccines. However, if this cannot be avoided, the vaccine

should be injected into separate limbs. In such cases, you should be aware that the side effects may be more intense.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant, think you may be pregnant, or plan to become pregnant. You should discuss with your doctor whether you should receive CELVAPAN.

The vaccine may be used during breast-feeding.

Driving and using machines

Some effects mentioned under the Possible side effects section may affect your ability to drive or use machines.

How CELVAPAN is given

Your doctor or nurse will administer the vaccine in accordance with official recommendation.

The vaccine will be injected into a muscle (usually in the upper arm).

Adults and elderly

A dose (0.5 ml) of the vaccine will be given.

A second dose of the vaccine should be given after an interval of at least three weeks.

Children and adolescents aged 6 months to 17 years of age

If it is considered that you or your child needs to be vaccinated, you/he/she may receive one dose of 0.5 ml vaccine and a second dose of 0.5 ml at least three weeks later.

Children aged less than 6 months

Vaccination is not currently recommended in this age group.

When CELVAPAN is given for the first dose, it is recommended that CELVAPAN (and not another vaccine against H1N1) be given for the complete vaccination course.

Possible side effects

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

Allergic reactions may occur following vaccination, in rare cases leading to shock. Doctors are aware of this possibility and have emergency treatment available for use in such cases.

In the clinical studies with a similar vaccine, most side effects were mild in nature and short term. 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 frequency of possible side effects listed below is defined using the following convention:

very common (affects more than 1 user in 10)

common (affects 1 to 10 users in 100)

uncommon (affects 1 to 10 users in 1,000)

rare (affects 1 to 10 users in 10,000)

very rare (affects less than 1 user in 10,000)

Side effects observed with CELVAPAN (H5N1)

The side effects listed below have occurred with CELVAPAN (H5N1) in clinical studies in adults, including the elderly:

Very common:

- pain at injection site

Common:

- runny nose and sore throat,
- headache, dizziness, vertigo (motion sickness),
- sweating more than usual,
- joint or muscle pain,
- chills, fatigue (feeling tired), malaise (generally feeling unwell), fever,
- tissue hardening, redness, swelling or bruising at the injection site

Uncommon:

- numb, tingling or prickly skin,
- dry throat,
- swollen glands,
- insomnia (difficulty sleeping), restlessness,
- impaired perception of touch, pain, heat and cold, sleepiness,
- conjunctivitis (an inflammation of the eye),
- sudden hearing loss,
- reduced blood pressure,
- shortness of breath, cough, congestion of the nose,
- nausea, vomiting, diarrhoea, stomach pain,
- rash, itching,
- irritation at the injection site

Rare:

- ear pain, clumsiness of vaccinated arm

These side effects usually disappear within 1-2 days without treatment. If they persist, CONSULT YOUR DOCTOR.

From ongoing clinical trials, where a first dose of CELVAPAN (H1N1) was given to a limited number of adults, elderly and children similar adverse events were observed in the first days after vaccination to those previously seen with CELVAPAN (H5N1) vaccine.

- CELVAPAN H1N1 side effects observed during the pandemic flu vaccination program

The side effects listed below have occurred with CELVAPAN H1N1 in adults and children during the pandemic flu vaccination program.

Allergic reactions, including anaphylactic reactions leading to a dangerous decrease in blood pressure which, if untreated, may lead to shock.

Fits

Pain in arms and/or legs

Flu-like illness

Swelling of tissue just below the skin.

- Side effects observed with flu vaccines given routinely every year

The side effects listed below have occurred in the days or weeks after vaccination with vaccines given routinely every year to prevent flu. These side effects may occur with CELVAPAN.

Uncommon:

- generalized skin reactions including urticaria (hives)

Rare:

- 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.
- Fits
- Severe stabbing or throbbing pain along one or more nerves
- Low blood platelet count which can result in bleeding or bruising

Very rare:

- 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

If any of these side effects occur, please tell your doctor or nurse immediately.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

How to store CELVAPAN

Keep out of the reach and sight of children.

Do not use CELVAPAN after the expiry date which is stated on the carton. 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 vial is to be used within a maximum of 3 hours less.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Further Information

What CELVAPAN contains

Active substance

Whole virion influenza vaccine, inactivated, containing antigen of pandemic strain*:

A/California/07/2009 (H1N1) 7.5 micrograms** per 0.5mL dose

* propagated in Vero cells (continuous cell line of mammalian origin)

** haemagglutinin

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

Other ingredients

The other ingredients are: trometamol, sodium chloride, water for injections, polysorbate 80.

What CELVAPAN looks like and contents of the pack

CELVAPAN is an off-white, opalescent, translucent liquid. One pack of CELVAPAN contains 20 multidose vials of 5 ml suspension for injection for 10 doses.

Distributor

Supplied in Australia by:
Baxter Healthcare Pty Limited
1 Baxter Drive,
Old Toongabbie
NSW 2146, Sydney

Supplied in New Zealand by:
Baxter Healthcare Limited

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