

B. PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

CELVAPAN suspension for injection

Pandemic influenza vaccine (H1N1) (whole virion, Vero cell derived, inactivated)

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.

In this leaflet

1. What Celvapan is and what it is used for
2. Before you receive Celvapan
3. How Celvapan is given
4. Possible side effects
5. How to store Celvapan
6. Further information

1. WHAT CELVAPAN IS AND WHAT IT IS USED FOR

Celvapan is a vaccine to prevent pandemic 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.

2. 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 section 6. 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 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 section 4 “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 vaccines 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 section 4. “Possible side effects” may affect your ability to drive or use machines.

3. 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.

4. 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. The side-effects are generally similar to those related to the seasonal 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 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 the injection site, headache, fatigue (feeling tired)

Common:

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

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,
- rash, itching,
- irritation at the injection site

Rare:

- ear pain, stiff arm

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

- Clinical Trials with Celvapan (H1N1)

Safety findings after the first and second dose of vaccine given during an ongoing clinical trial of Celvapan (H1N1) in adults and elderly (18 years of age and older) suggest a similar safety profile to that reported for influenza vaccines using an H5N1 strain. Safety results from another ongoing Celvapan H1N1 study involving children and adolescents aged 3-17 years were similar to the findings of the adults and elderly trial. However, in the children's trial injection site pain was reported at a higher rate (very common) than in adults, and both headache and fatigue were reported at a lower rate (common) than in adults. In children aged 3 to 8 years, fever after both the 1st and 2nd vaccination was reported commonly, but no fever was reported in children and adolescents aged 9 to 17 years.

During a clinical trial involving children aged 6 to 35 months, the following reactions were very common: sleep disturbance, loss of appetite, crying, irritability and sleepiness.

- 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 of fever

Pain in arms and or legs (in the majority of cases reported as pain in the vaccination arm)

Flu-like illness

Swelling of tissue just below the skin.

Pandemic observational study

In an ongoing safety study involving 240 children (over 5 years) and adults as well as 53 children aged 6 months to 5 years the following adverse reactions were reported at a very common frequency:

Children above 5 years of age, adolescents and adults:

Injection site reactions, tiredness, headache, muscle pain, stomach upset.

Children aged 6 months to 5 years:

Injection site reactions, drowsiness, irritability, loss of appetite.

- 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.
- 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.

5. 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.

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.

6. 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 0.5 ml 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 a clear to opalescent, translucent liquid.

One pack of Celvapan contains 20 multidose vials of 5 ml suspension for injection for 10 doses.

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This leaflet was approved in

This medicine has been authorised under “Exceptional Circumstances”. The European Agency (EMA) will regularly review any new information on the medicine and this package leaflet will be updated as necessary.

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 medical or health care professionals only:

Prior to administration, the vaccine should be allowed to reach room temperature and the vial should be shaken well.

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.

The vaccine should not be administered intravascularly.

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