PACKAGE LEAFLET: INFORMATION FOR THE USER

CELTURA suspension for injection in pre-filled syringe
Pandemic H1N1 Influenza Vaccine (surface antigen, inactivated, prepared in cell cultures, adjuvanted)

All information included in this package leaflet and in the labelling material accompanying this product has been printed in advance of its approval to facilitate the availability of the vaccine. For the most up-to-date information please consult the website of Paul-Ehrlich-Institut (PEI): http://www.pei.de

Read all of this leaflet carefully before you start receiving this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- 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 CELTURA IS AND WHAT IT IS USED FOR

CELTURA is a vaccine used to prevent influenza (flu) in an officially declared pandemic.

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

The vaccine works by causing the body to produce its own protection (antibodies) against the disease
As with all vaccines, CELTURA may not fully protect all persons who are vaccinated.

2. BEFORE YOU RECEIVE CELTURA

Do not take CELTURA if you:
- have experienced serious allergic reaction (i.e. life-threatening) to any of the constituents of CELTURA,
- are allergic (hypersensitive) to influenza vaccines or any of the ingredients of CELTURA,
- are allergic to cetyltrimethylammonium bromide (CTAB).

Take special care with CELTURA if you:
- feel feverish,
- have any illness or infection,
- are having immunosuppressive therapy, e.g. corticosteroid treatment or chemotherapy for cancer, or if you have any condition which makes you prone to infections (immunodeficiency conditions).

In any of these cases, TELL YOUR DOCTOR, 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.

Taking other medicines
Please tell your doctor if you are taking or have recently taken any other medicines, including medicines

obtained without a prescription. There is no data on administration of CELTURA at the same time with other vaccines. If another vaccine is required at the same time, then the injection should be carried out on a different limb. In such cases, the side effects may be more intense.

Pregnancy and breast-feeding
There is no information on the use of CELTURA in pregnant women. Your doctor needs to assess the benefits and potential risks of giving you the vaccine if you are pregnant. Please tell your doctor if you are/may be pregnant or intend to become pregnant.

The vaccine may be used during lactation.

Driving and using machines
The vaccine is unlikely to produce any effect on the ability to drive and use machines.

3. HOW TO RECEIVE CELTURA

Your doctor or nurse will administer the vaccine in accordance with official recommendations.
The vaccine will be injected into a muscle (usually in the upper arm).

Adults (18-50):
A dose (0.25 ml) of the vaccine will be given.
Clinical data suggest that a single dose may be sufficient.
If a second dose of vaccine is administered there should be an interval of at least three weeks between the first and second dose.

Elderly (>50):
A dose (0.25 ml) of the vaccine will be given.
A second dose of 0.25 ml vaccine should be given after an interval of at least three weeks.

Children and adolescents 3-17 years of age:
You or your child will receive one dose of 0.25 ml vaccine.
Clinical data suggest that a single dose may be sufficient.
If a second dose of vaccine is administered there should be an interval of at least three weeks between the first and second dose.

Children 6-35 months of age:
Your child will receive one dose of 0.25 ml vaccine and a second dose of 0.25 ml at least three weeks later.

Children aged less than 6 months of age:
Vaccination is currently not recommended in this age group.

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

4. POSSIBLE SIDE EFFECTS

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

Very common (in more than 1 out of 10 people) to common (in more than 1 out of 100 people, but less than 1 in 10).
- redness
- swelling or pain at the site of injection
- bruising or hardening of the skin at the injection site

In some cases the effects may also include
- raised temperature (fever)

- malaise (generally feeling unwell)
- shivering
- tiredness
- headache
- sweating
- pain in muscles and joints

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

Uncommon (in more than 1 out of 1,000 people, but less than 1 in 100).
- generalised skin reactions including itching
- bumps on the skin or a non-specific rash

Rare (in more than 1 out of 10,000 people, but less than 1 in 1,000).
- neuralgia (pain along a nerve)
- numbness or tingling sensations
- convulsions (fits)
- transient thrombocytopenia (a low platelet count in the blood which can result in bleeding or bruising). 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

Very rare (in less than 1 in 10,000).
- vasculitis (inflammation of the blood vessels which can cause skin rashes, joint pain and kidney problems) and exudative erythema multiforme
- 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 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 CELTURA

Keep out of the reach and sight of children.

Do not use CELTURA after the expiry date which is stated on the carton and the label after EXP. The expiry date refers to the last day of that month.
Store in a refrigerator (2°C - 8°C). Do not freeze. Store in the original package in order to protect from light.
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 CELTURA contains

- Active Substance:
  CELTURA does not contain live virus particles and so it cannot cause Pandemic influenza. The active ingredients of the vaccine are purified viral proteins (called haemagglutinin and neuraminidase). They are isolated from the surface of influenza virus particles, which are grown in Madin Darby Canine Kidney (MDCK) cells (this is the special cell culture in which the influenza virus is grown). These viral proteins are prepared from the strain of influenza virus that complies with the WHO recommendations and EU decision in an officially declared Pandemic situation.
  One dose (0.25 ml) of the vaccine contains at least 3.75 micrograms of haemagglutinin from the following recommended influenza virus strain:

A/California/7/2009 (H1N1)v-like strain used (X-179A)

- Adjuvant:
  The vaccine contains an 'adjuvant' (a compound containing squalene) to stimulate a better response. The adjuvant includes also polysorbate 80 and sorbitan trioleate in a citrate buffer.

- Other Ingredients:
  The other ingredients are: sodium chloride, potassium chloride, potassium dihydrogen phosphate, disodium phosphate dihydrate, magnesium chloride hexahydrate, calcium chloride dihydrate, sodium citrate, citric acid and water for injections.

What CELTURA looks like and contents of the pack
CELTURA is a milky-white liquid.
It is provided in:
- ready-to-use syringe, containing a single dose (0.25 ml) for injection.

Marketing Authorisation Holder and Manufacturer
Novartis Vaccines and Diagnostics GmbH
Emil-von-Behring-Strasse 76
D-35041 Marburg
GERMANY

This leaflet was approved in 04/2010.

PACKAGE LEAFLET: INFORMATION FOR THE USER

CELTURA suspension for injection in multidose container
Pandemic H1N1 Influenza Vaccine (surface antigen, inactivated, prepared in cell cultures, adjuvanted)

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- have any illness or infection,
- are having immunosuppressive therapy, e.g. corticosteroid treatment or chemotherapy for cancer, or if you have any condition which makes you prone to infections (immunodeficiency conditions),

In any of these cases, TELL YOUR DOCTOR, 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.

Taking other medicines
Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. There is no data on administration of CELTURA at the same time with other vaccines. If another vaccine is required at the same time, then the injection should be carried out on a different limb. In such cases, the side effects may be more intense.

Pregnancy and breast-feeding
There is no information on the use of CELTURA in pregnant women. Your doctor needs to assess the benefits and potential risks of giving you the vaccine if you are pregnant. Please tell your doctor if you are/may be pregnant or intend to become pregnant.
The vaccine may be used during lactation.

Driving and using machines
The vaccine is unlikely to produce any effect on the ability to drive and use machines.

Important information about some of the ingredients of CELTURA
This medicinal product in multidose vial contains thiomersal as a preservative and it is possible that you may experience an allergic reaction. Tell your doctor if you have any known allergies.

3. HOW TO RECEIVE CELTURA

Your doctor or nurse will administer the vaccine in accordance with official recommendations.
The vaccine will be injected into a muscle (usually in the upper arm).

Adults (18-50):
A dose (0.25 ml) of the vaccine will be given.
Clinical data suggest that a single dose may be sufficient.
If a second dose of vaccine is administered there should be an interval of at least three weeks between the first and second dose.

Elderly (>50):
A dose (0.25 ml) of the vaccine will be given.
A second dose of 0.25 ml vaccine should be given after an interval of at least three weeks.

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You or your child will receive one dose of 0.25 ml vaccine.
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Children aged less than 6 months of age:
Vaccination is currently not recommended in this age group.

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

4. POSSIBLE SIDE EFFECTS

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

Very common (in more than 1 out of 10 people) to common (in more than 1 out of 100 people, but less than 1 in 10)
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Rare (in more than 1 out of 10,000 people, but less than 1 in 1,000).
- neuralgia (pain along a nerve)
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- convulsions (fits) or transient thrombocytopenia (a low platelet count in the blood which can result in bleeding or bruising)
- 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.

Very rare (in less than 1 in 10,000).
- vasculitis (inflammation of the blood vessels which can cause skin rashes, joint pain and kidney problems) and exudative erythema multiforme.
- 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 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 CELTURA

Keep out of the reach and sight of children.

Do not use CELTURA after the expiry date which is stated on the carton and the label after EXP. The expiry date refers to the last day of that month.
After withdrawal of the first dose, the vaccine should be used within 24 hours. Between uses, return the multidose vial to the recommended storage conditions between 2° and 8°C.
Store in a refrigerator (2°C - 8°C). Do not freeze. Store in the original package in order to protect from light.
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 CELTURA contains

- Active Substance:
  CELTURA does not contain live virus particles and so it cannot cause Pandemic influenza. The active ingredients of the vaccine are purified viral proteins (called haemagglutinin and neuraminidase). They are isolated from the surface of influenza virus particles, which are grown in Madin Darby Canine Kidney (MDCK) cells (this is the special cell culture in which the influenza virus is grown). These viral proteins are prepared from the strain of influenza virus that complies with the WHO recommendations and EU decision in an officially declared Pandemic situation.
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  A/California/7/2009 (H1N1)v-like strain used (X-179A)
- Adjuvant:
  The vaccine contains an 'adjuvant' (a compound containing squalene) to stimulate a better response. The adjuvant includes also polysorbate 80 and sorbitan trioleate in a citrate buffer.

- Other Ingredients:
  The other ingredients are: sodium chloride, potassium chloride, potassium dihydrogen phosphate, disodium phosphate dihydrate, magnesium chloride hexahydrate, calcium chloride dihydrate, sodium citrate, citric acid, thiomersal and water for injections.

What CELTURA looks like and contents of the pack
CELTURA is a milky-white liquid.
It is provided in:
- vials containing seventeen doses (0.25 ml each) for injection.

Marketing Authorisation Holder and Manufacturer
Novartis Vaccines and Diagnostics GmbH
Emil-von-Behring-Strasse 76
D-35041 Marburg
GERMANY

This leaflet was approved in 04/2010.

The following information is intended for medical or healthcare professionals only:

The vaccine should be allowed to reach room temperature before use. The volume of CELTURA (5 ml) corresponds to 17 vaccine doses. Before use the vial should be gently shaken. Shaking results in a milky-white liquid. In the event of variation being observed, discard the vaccine. Each vaccine dose of 0.25 ml is withdrawn into a syringe for injection. The needle used for withdrawal must be replaced by a needle suitable for injection.