

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 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 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

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.

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:

- generalised 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.

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 an off-white, opalescent, translucent liquid.

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

Marketing Authorization Holder:

Baxter AG
Industriestrasse 67
A-1221 Vienna
Austria

Manufacturer:

Baxter AG
Uferstrasse 15
A-2304 Orth/Donau
Austria

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder given below:

België/Belgique/Belgien

Baxter Belgium SPRL
Bd. de la Plaine/Pleinlaan 5
B-1050 Brussel/Bruxelles/Brüssel
Tél/Tel: + 32 2 650 1711

Luxembourg/Luxemburg

Baxter Belgium SPRL
Bd. de la Plaine/Pleinlaan 5
B-1050 Bruxelles/Brüssel
Tél/Tel: + 32 2 650 1711

България

ТП Бакстер АД
ул. Рачо Димчев 4
София 1000
тел.: + 359 2 9808482

Magyarország

Baxter Hungary Kft
Népfürdő u. 22.
H-1138 Budapest
Tel.: +361 202 19 80

Česká republika

Baxter Czech spol.s r.o.
Opletalova 55
CZ-110 00 Praha 1
Tel.: +420 225774111

Danmark

Baxter A/S
Gydevang 43
DK-3450 Allerød
Tlf: + 45 48 16 64 00

Deutschland

Baxter Deutschland GmbH
Edisonstraße 4
D-85716 Unterschleißheim
Tel: + 49 89 31701-0

Eesti

AS Oriola
Kungla 2
EE-76505 Saue
Tel.: + 372 6 515 100

Ελλάδα

Baxter (Hellas) E.Π.Ε.
Εθνάρχου Μακαρίου 34 & Αθηνόδωρου
Ηλιούπολη
GR-163 41 Αθήνα
Τηλ.: +30-210-99 87 000

España

Baxter S.L.
Pouet de Camilo, 2
E- 46394 Ribarroja del Turia (Valencia)
Tel: + 34 96 2722800

France

Baxter SAS
6 Avenue Louis Pasteur
F-78310 Maurepas
Tél: + 33 1 3461 5050

Ireland

Baxter Healthcare Ltd
Unit 7 Deansgrange Industrial Estate
IRL-Blackrock, Dublin
Tel: + 44 1635 206345

Ísland

Icepharma hf.
Lynghálsi 13
IS-110 Reykjavík
Sími: + 354 540 80-00

Malta

Baxter Healthcare Ltd
Wallingford Road, Compton Newbury
Berkshire RG20 7QW - UK
Tel.: + 44 1635 206345

Nederland

Baxter B.V.
Kobaltweg 49
NL-3542 CE Utrecht
Tel: + 31 30 2488911

Norge

Baxter AS
Gjerdrumsvei 11
N-0484 Oslo
Tlf: + 47 22 58 4800

Österreich

Baxter Vertriebs GmbH
Landstraßer Hauptstraße 99 /Top 2A
A-1031 Wien
Tel.: +43 1 71120 0

Polska

Baxter Polska Sp. z o.o.
ul. Kruczkowskiego 8
PL-00-380 Warszawa
Tel.: + 48 22 4883 777

Portugal

Baxter Médico Farmacêutica Lda
Sintra Business Park
Zona Industrial da Abrunheira, Edifício 10
P-2710-089 Sintra
Tel: + 351 21 925 25 00

România

FARMACEUTICA REMEDIA S.A.
78 Metalurgiei Blv., 4th district
041836 Bucharest, ROMANIA
Tel.: + 40-21-321 1640

Slovenija

Baxter d.o.o.
Železna cesta 18
1000 Ljubljana
Tel.: + 386 1 420 16 80

Slovenská republika

Baxter AG, o. z.
Dúbravská cesta 2
SK-841 04 Bratislava
Tel: + 421 2 59418455

Italia

Baxter S.p.A.
Piazzale dell'Industria, 20
I-00144 Roma
Tel: + 39 06 324911

Κύπρος

Baxter (Hellas) E.Π.Ε.
Εθνάρχου Μακαρίου 34 & Αθηνοδώρας
Ηλιοπούλη
GR-163 41 Αθήνα
Τηλ.: +30-210-99 87 000

Latvija

Baxter AG Latvijas filiāle
Dzelzavas iela 117
LV 1021 RĪGA
Tel.: +371 67784784

Lietuva

UAB TAMRO atstovybė
S. Žukausko g. 29-1
LT-09129 Vilnius
Tel.: + 370 5 269 16 91

Suomi/Finland

Baxter Oy
PL 270
Valimotie 15 A
FIN-00381 Helsinki
Puh/Tel: + 358 9 8621111

Sverige

Baxter Medical AB
Torshamnsgatan 35
Box 63
S-164 94 Kista
Tel: + 46 8 6326400

United Kingdom

Baxter Healthcare Ltd
Wallingford Road, Compton Newbury
Berkshire RG20 7QW - UK
Tel: + 44 1635 206345

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.