

B. PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

HUMENZA Suspension and emulsion for emulsion for injection Pandemic influenza vaccine (H1N1) (split virion, inactivated, adjuvanted)

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

1. WHAT HUMENZA IS AND WHAT IT IS USED FOR

HUMENZA 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 (signs) 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 defence system) will produce its own protection (antibodies) against the disease. None of the ingredients in the vaccine can cause flu.

2. BEFORE YOU RECEIVE HUMENZA

You should not receive HUMENZA:

- if you have previously had a sudden life-threatening allergic reaction to any ingredient of HUMENZA (these are listed at the end of the leaflet) or to any of the substances that may be present in trace amounts as follows: ovalbumin, egg and chicken proteins, neomycin, octoxinol-9, formaldehyde. 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 HUMENZA:

- if you have had any allergic reaction other than a sudden life-threatening allergic reaction to any ingredient contained in the vaccine, to thiomersal, ovalbumin, egg and chicken proteins, neomycin, octoxinol-9, formaldehyde (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 should advise whether you could still be vaccinated with HUMENZA,

- if you are having a blood test to look for evidence of infection with certain viruses. In the first few weeks after vaccination with HUMENZA the results of these tests may not be correct. Tell the doctor requesting these tests that you have recently been given HUMENZA.
- as with all vaccines, HUMENZA may not fully protect all persons who are vaccinated.

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.

Children below 6 months of age:

HUMENZA is not recommended in children below 6 months of age.

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 HUMENZA 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, plan to become pregnant or if you are breastfeeding. You should discuss with your doctor whether you should receive HUMENZA.

Driving and using machines

Some of the effects mentioned under section 4 “Possible side effects” may affect the ability to drive or use machines.

Important information about some of the ingredients of HUMENZA

This medicine contains thiomersal as a preservative and it is possible that you may experience an allergic reaction. Tell the doctor if you have any known allergies.

3. HOW HUMENZA IS GIVEN

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

The vaccine will be injected into a muscle, preferably in the upper arm or the front of the thigh (depending on the muscle mass).

Children from 3 years of age, adolescents and adults up to 60 years of age:

One dose of 0.5 ml of the vaccine will be given.

Clinical data suggest that a single dose may be sufficient.

If a second dose is administered there should be an interval of at least three weeks between the first and second dose.

Elderly above 60 years of age:

One dose of 0.5 ml of the vaccine will be given.

A second dose of vaccine should be given after an interval of at least 3 weeks.

Children from 6 months to less than 3 years of age:

One half-dose of 0.25 ml of the vaccine will be given.

If a second dose of 0.25 ml is given, this will be administered at least three weeks after the first dose.

Children below 6 months of age:

Vaccination is currently not recommended in this age group

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, HUMENZA 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.

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)

During a clinical study conducted with HUMENZA in adults and elderly, the side effects listed below have been observed.

Very common: headache, muscular pain, injection site pain.

Common: feeling generally unwell, shivering, fever. At the injection site: hardness, redness, swelling, bruising.

During clinical studies conducted with HUMENZA in children and adolescents, the side effects listed below have been observed.

Adolescent from 9 to 17 years old:

Very common: headache, feeling generally unwell, muscular pain, shivering. At the injection site: pain, redness, swelling, hardness.

Common: fever, sore throat, injection site bruising.

Children from 3 to 8 years old:

Very common: feeling generally unwell, muscular pain, headache, shivering, fever. At the injection site: pain, redness, swelling, bruising, hardness.

Common: injection site warmth.

Children from 24 to 35 months old:

Very common: feeling generally unwell, muscular pain, shivering, fever. At the injection site: pain, redness, hardness, swelling.

Common: injection site bruising, headache, cough.

Children from 12 to 23 months old:

Very common: appetite lost, irritability, drowsiness, fever, abnormal crying. At the injection site: pain, redness, hardness, swelling.

Common: injection site bruising, vomiting, cough.

Children from 6 to 11 months old:

Very common: irritability, crying abnormal, appetite lost, drowsiness, fever, vomiting. At the injection site: pain, redness, hardness, swelling.

Common: injection site bruising, diarrhoea.

In all age groups, the side effects listed above usually disappeared without treatment within 1 to 3 days after onset.

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 HUMENZA.

Very rare:

- Skin reactions that may spread throughout the body including itchiness of the skin (pruritus, urticaria), rash.
- Side effects related to the central nervous system:
 - Pain located on the nerve route (neuralgia),
 - Differences in the perception of touch, pain, heat and cold (paraesthesia),
 - Convulsions associated with fever,
 - Neurological disorders that may result in stiff neck, confusion, numbness, pain and weakness of the limbs, loss of balance, loss of reflexes, paralysis of part or all the body (encephalomyelitis, neuritis, Guillain-Barré Syndrome).
- Temporary reduction in the number of certain types of particles in the blood called platelets; a low number of these can result in excessive bruising or bleeding (transient thrombocytopenia), temporary swelling of the glands in the neck, armpit or groin (transient lymphadenopathy).
- Allergic reactions:
 - In rare cases leading to shock (a failure of the circulatory system to maintain adequate blood flow to the different organs leading to medical emergency).
 - Including swelling most apparent in the head and neck, including the face, lips, tongue, throat or any other part of the body (angioedema) in very rare cases.
- Vessel inflammation (vasculitis) which may result in skin rashes and in very rare cases in temporary kidney problems.

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 HUMENZA

Keep out of the reach and sight of children.

Before the vaccine is mixed:

Do not use the antigen (suspension) and the adjuvant (emulsion) 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.

Keep the vial in the outer carton in order to protect from light.

After the vaccine is mixed:

HUMENZA should be stored in a refrigerator (2°C-8°C) and should be used within 24 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 HUMENZA contains

HUMENZA consists of two vials: one vial containing the antigen (suspension) and one vial containing the adjuvant (emulsion), which are mixed prior to use.

After mixing:

- Active substance:

Split Influenza virus*, inactivated, containing antigen equivalent to:

A/California/7/2009 (H1N1)-like strain (NYMC X179A).....	3.8 micrograms** per 0.5 ml dose
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* propagated in eggs

** expressed in microgram haemagglutinin

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

- Adjuvant:

The adjuvant (AF03) is composed of squalene (12.4 milligrams), sorbitan oleate (1.9 milligrams), polyoxyethylene cetostearyl ether (2.4 milligrams) and mannitol (2.3 milligrams), per 0.5 ml dose

- Other ingredients:

The other ingredients are: thiomersal (11.3 micrograms per 0.5 ml dose), sodium chloride, potassium chloride, disodium phosphate dihydrate, potassium dihydrogen phosphate and water for injections.

What HUMENZA looks like and contents of the pack

One pack contains:

- One pack containing 10 vials of 1.5 ml of suspension (antigen).
- One pack containing 10 vials of 4.5 ml of emulsion (adjuvant).

The antigen is a colourless limpid to opalescent suspension.

The adjuvant is a white opaque emulsion.

After mixing the content of antigen vial into the adjuvant vial, HUMENZA is an emulsion for injection in a multidose vial containing 10 doses of 0.5 ml. The emulsion is white, opaque.

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HUMENZA has been given "conditional approval".

This means that there is more evidence to come about this medicine.

The European Medicines Agency will 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 web site:
<http://www.ema.europa.eu>

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

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event following the administration of the vaccine.

HUMENZA consists of 2 separate vials:

- One vial containing the antigen (suspension)
- One vial containing the adjuvant (emulsion)

Before use, the two components should be mixed.

Instructions for mixing the vaccine:

1. Before extemporaneous mix, the two vials (antigen and adjuvant) should be allowed to reach room temperature and must be gently swirled between hands and inspected visually for any foreign particulate matter and/or abnormal physical appearance. In the event of either being observed (including rubber particles from the stopper), the vaccine should be discarded.
2. The vaccine is mixed by withdrawing with a sterile syringe and needle the entire content of the antigen vial and adding it into the adjuvant vial.
3. After the addition of the antigen to the adjuvant, the mixture should be gently shaken by at least 5 rotating movements. After mixing, the vaccine is a white opaque emulsion.
4. The volume of HUMENZA after mixing is at least 6 ml and allows the withdrawal of several doses (multidose vial). For the dose to be administered, see recommended posology in section 3 "How HUMENZA is given".
5. After mixing HUMENZA should be stored in a refrigerator (2°C-8°C) (never place in the freezer) and should be used within 24 hours.
6. To facilitate tracking and timely disposal of partially used vials, it is suggested that the date and hour of mixing be clearly written on the label of adjuvant vial.

Instructions for the administration of the vaccine:

1. Before injection the vaccine should be allowed to reach room temperature by gently swirling the vial between hands (not more than 5 minutes).
2. Prior to each administration, the multidose vial should be gently shaken by at least 5 rotating movements.
3. The content of the multidose vial as well as the content of the syringe after withdrawal should be inspected visually. The vaccine is of a white opaque emulsion appearance. If deviations from this description and/or any foreign particulate matter are observed (including rubber particles from the stopper), the vaccine should be discarded.
4. Each vaccine dose of 0.5 ml or 0.25 ml (half-dose) is withdrawn with a new sterile syringe for injection and administered intramuscularly.

HUMENZA should under no circumstances be administered intravascularly.

A partially used multidose vial must be discarded immediately if:

- Sterile dose withdrawal has not been fully observed.
- There is any suspicion that the partially used vial has been contaminated.
- There is visible evidence of contamination, such as change in appearance.

In order to keep the traceability of the product received by each vaccinee the name of the vaccine and the lot number should be recorded by using the stickers provided in the pack containing both the antigen and adjuvant vials.

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