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PACKAGE LEAFLET: INFORMATION FOR THE USER

PANENZA

suspension for injection in multidose vial

PANDEMIC INFLUENZA VACCINE (H1N1) (SPLIT VIRION, INACTIVATED)

Read all of this leaflet carefully before you are given this medicine.
- 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 PANENZA IS AND WHAT IT IS USED FOR

PANENZA is a vaccine against a 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.

These side effects usually disappeared without treatment within 1 to 3 days after onset.

During a clinical study in children and adolescents (from 24 months to 17 years of age), the following side effects have been observed:
Very common:
- Headache, muscular pain,
- Feeling generally unwell, shivering,
- At the injection site: pain, redness

Common:
- Fever,
- At the injection site: swelling, hardness, bruising.

These side effects usually disappeared without treatment within 1 to 3 days after onset.

During a clinical study in children (from 6 months to 23 months), the following side effects have been observed:
Very common:
- Drowsiness
- Abnormal crying
- Appetite lost
- Irritability
- At the injection site: tenderness, redness

Common:
- Vomiting
- Fever
- At the injection site: swelling, hardness, bruising.

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 PANENZA.
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 occurs, 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 PANENZA

Keep out of the reach and sight of children.

Do not use PANENZA 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 first opening, use PANENZA within 7 days if stored in a refrigerator (2°C – 8°C).

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.

2. BEFORE YOU RECEIVE PANENZA

Do not take PANENZA:
- if you previously had a sudden life threatening allergic reaction to any ingredient of PANENZA (they are listed at the end of the leaflet) or to any of the substances that may be present in trace amounts as follows: egg and chicken protein, ovalbumin, 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 pharmacist before having this vaccine.

Take special care with PANENZA:
- if you had an allergic reaction other than a life-threatening allergic reaction to any ingredient contained in the vaccine, to thiomersal, to egg, chicken protein, ovalbumin, 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 a problem, but your doctor should advise whether you could still be vaccinated with PANENZA,
- if you are having a blood test to look for evidence of infection with certain viruses. In the first few weeks after vaccination with PANENZA the results of these tests may not be correct. Tell the doctor requesting these tests that you have recently been given PANENZA.
- as with all vaccines, PANENZA 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.

Taking other medicines

Please tell the 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 are no data on administration of the vaccine PANENZA with other vaccines.
However, if this cannot be avoided, the other vaccine should be injected into the other limb. 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 PANENZA.

Driving and using machines

No studies on the effects on the ability to drive or use machines have been performed.
The vaccine is unlikely to produce any effect on the ability to drive and use machines.

Important information about some of the ingredients of PANENZA

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 PANENZA IS GIVEN

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 up to 60 years of age, adolescents and children from the age of 9 years onwards:
One dose (0.5 ml).
A second dose could be given at an interval of at least 3 weeks between the first and second dose.

Elderly (>60 years of age):
One dose of 0.5 ml at an elected date.
A second dose of vaccine should be given after an interval of at least 3 weeks.

Children from 3 years to 8 years of age:
One dose (0.5 ml) is given at an elected date.
A second dose of vaccine should be given after an interval of at least 3 weeks.

Children from 6 months to 35 months of age:
One half-dose (0.25 ml) is given at an elected date.
A second half-dose of vaccine should be given after an interval of at least 3 weeks.

Children less than 6 months of age:
PANENZA is not recommended in children less than 6 months of age.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, PANENZA 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)
Not known (frequency cannot be estimated from the available data).

During a clinical study conducted in adults and elderly, the following side effects have been observed:
Very common:
- Headache, muscular pain,
- Pain at the injection site

Common:
- Feeling generally unwell, shivering, fever,
- At the injection site: redness, swelling.

6. FURTHER INFORMATION

What PANENZA contains

- The active substance is:
Split Influenza virus*, inactivated, containing antigen equivalent to:
A/California/7/2009 (H1N1)v-like strain (NYMC X-179A) ..... 15 micrograms** per 0.5 ml dose

* propagated in eggs
** expressed in microgram haemagglutinin

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

- The other ingredients are:
thiomersal (45 micrograms per 0.5 ml dose), sodium chloride, potassium chloride, disodium phosphate dihydrate, potassium dihydrogen phosphate, and water for injections.

What PANENZA looks like and contents of the pack

PANENZA is a suspension for injection in a multidose vial (10 doses of 0.5ml) - Pack of 10 vials.
The suspension is colorless limpid to opalescent.

Marketing Authorisation Holder:

Sanofi Pasteur SA – 2, avenue Pont Pasteur – F-69007 Lyon – France

Manufacturer:

Sanofi pasteur - Parc Industriel d'Incarville – F-27100 Val de Reuil – France
Sanofi pasteur - Campus Mérieux – 1541, avenue Marcel Mérieux – F-69280 Marcy l'Etoile – France

This leaflet was last approved in November 2009

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.

Instructions for administration of the vaccine:
It is necessary to respect the good practices of asepsis at each step of handling.

Before injection the vaccine should be allowed to reach room temperature by gently swirling the vial between hands (not more than 5 minutes).

Shake before each use.

Each dose of vaccine must be withdrawn with a new syringe for injection and administered intramuscularly.

After first opening, the vaccine contained in the vial must be used within 7 days. To facilitate tracking and timely disposal of multidose vials, it is suggested that the date of opening be clearly written on the label.

Partially used multidose vials must be kept at the required temperature, i.e. between 2°C and 8°C (never place the product in a freezer).

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.

The vaccine is not to be injected directly into any blood vessel.

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 on paper or electronic support.

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

See also section 3. HOW PANENZA IS GIVEN

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