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, egg and chicken protein, ovalbumin, neomycin, octoxinol-9, formaldehyde. "Signs of an allergic reaction may include itching 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 allergy reaction other than a life-threatening allergic reaction to any ingredient contained in the vaccine, to thiomersal, to egg, to 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 of PANENZA will help to protect the environment.

If any of these side effects occurs, please tell your doctor or nurse immediately.

Making other medicines

Please talk to the doctor or nurse if you are taking or have recently been given any other medicines, including medicinal obtained without a prescription or has 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 case, you should be aware that the side effects may be more intense.

Pregnancy and breastfeeding

Tell your doctor if you are pregnant, think you may be pregnant, plan to become pregnant or 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 65 years of age, adolescents and children from the age of 3 years onwards:
  - One dose (0.5 ml).
  - One half-dose (0.25 ml) is given at an elected date.
  - A second dose of vaccine should be given after an interval of at least 3 weeks.

- Elderly (>60 years of age)
  - A second dose of vaccine should be given after an interval of at least 3 weeks.
  - 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.

4. FURTHER INFORMATION

What PANENZA contains

- The active substance is:
  - 3H influenza virus V1 (H1N1) split virion, inactivated.

- The following are contained in the vaccine:
  - Inactivated 3H influenza virus V1 (H1N1) split virion (NYMC X-179A) containing 15 micrograms**

- **Propagated in eggs
- **Expressed in Escherichia coli haemagglutinin
- **This vaccine complies with the WHO recommendation and EU decision for the pandemic.

- The other ingredients are:
  - Thiomersal (85 micrograms per 0.5 ml dose), sodium chloride, potassium chloride, disodium phosphate, sodium dihydrogen phosphate and water for injection.

What PANENZA looks like and contents of the pack

PANENZA is a suspension for injection in a multidose vial (10 doses of 0.5 ml).

PANENZA is supplied as a vial with a syringe for injection and administration.

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).

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

After opening, the vaccine contained in the multidose vial must be used within 3 weeks.

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

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 4 months to 15 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 terms:

- 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:

- Headache, malaise, fever
- Pain at the injection site
- Severe pain
- Skin rash, itching
- Anaphylactic reaction

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

See also section 3. HOW PANENZA IS GIVEN