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**Fluarix Tetra Vaccine Consent Form 2021**

*Please answer the questions below to allow us to assess your suitability to receive the 2021 the flu vaccination:*

|  |  |  |
| --- | --- | --- |
| **Question** | **Yes**  | **No** |
| Have you ever had a flu vaccine? |  |  |
| Have you ever had any problems after receiving a flu vaccine or any vaccine in the past? |  |  |
| Are you allergic to eggs or egg products? |  |  |
| Have you had any severe allergies (to anything) in the past? |  |  |
| Do you have a high fever or are you feeling unwell at present? |  |  |
| Do you have a history of Guillain Barre Syndrome (severe muscle weakness)? |  |  |
| Do you have any medical conditions that the GP or nurse should be aware of prior to you receiving a vaccination (such as a chronic illness, bleeding disorder, do not have a functioning spleen, taking an immunosuppressant or undergoing chemotherapy / radiotherapy)? |  |  |
| **Women Only** – The flu vaccine can be given safely during any stage of pregnancy <http://www.immunise.health.gov.au>.Are you planning a pregnancy, currently pregnant or breast-feeding? |  |  |

The flu vaccine is very safe and generally, people do not have any reaction. The most common side effects are tenderness, swelling and redness at the injection site, which usually disappears after a couple of days. A small percentage of people may experience a mild fever and feel unwell for a few days – this is not the flu. These symptoms will clear up within a few days. It is recommended that all people who receive the flu vaccination remain in the Health Service for a period of 15 minutes in case of an allergic reaction.

I have read and understood this information and the Consumer Medicine Information (shown on the following page) for this vaccine. I consent to receiving a flu vaccine injection.

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ DOB: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Organisation: University of Southern Queensland Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Office Use Only:**

Nurse Immuniser: Skye Ruka Christine Schoenfisch Mark Wager

Vaccine Batch: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Expiry Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**FLUARIX TETRA Inactivated Split Influenza Vaccine Consumer Medicine Information**

This answers some of the common questions about FLUARIX TETRA vaccine. It does not contain all the available information. It does not take the place of talking to the medical practitioner.

All medicines and vaccines have risks and benefits. Your doctor has weighed the possible risks of you or your child having FLUARIX TETRA against the expected benefits. If you have any concerns about receiving FLUARIX TETRA talk to your doctor, nurse practitioner or registered nurse.

**What Fluarix Tetra is used for**

FLUARIX TETRA is used to help prevent certain types of influenza. The vaccine works by causing the body to produce its own protection (antibodies) against four different types of influenza virus. The types of influenza antigen contained in FLUARIX TETRA may change from one year to another. Each year, the Australian Influenza Vaccine Committee (AIVC) recommends which ones to include. This decision is based on the types of influenza virus thought most likely to occur during the next flu season. Therefore, influenza vaccination is recommended every year. Please note that FLUARIX TETRA will only protect you against the four types of influenza virus used to make the vaccine. It will not protect you from influenza caused by other types of influenza virus or from infections with other agents causing flu-like symptoms (such as the common cold). FLUARIX TETRA cannot give you or your child influenza because the viruses in the vaccine have been killed. Influenza is an infectious illness and is spread by small droplets from the nose, throat or mouth of an infected person. The most common symptoms of influenza include fever, sore throat, runny nose, coughing, general aches and pains, headache, weakness and tiredness, Most people recover completely within a week. The risk of serious complications (e.g. pneumonia and death) is greater in very young, very old and chronically ill persons. FLUARIX TETRA can be used in adults and children older than 6 months of age.

**Before you are given FLUARIX TETRA** - **When you or your child must not be given FLUARIX TETRA** FLUARIX TETRA must not be given if you or your child:

• have had an allergic reaction to FLUARIX TETRA or any of the ingredients listed at the end of this leaflet

• have had an allergic reaction or became unwell after any other influenza vaccine (e.g. Fluvax, Vaxigrip etc)

Some of the symptoms of an allergic reaction may include:

• shortness of breath

• wheezing or difficulty breathing

• swelling of the face, lips, tongue or other parts of the body

• rash, itching or hives on the skin

If you are not sure whether you or your child should have FLUARIX TETRA, talk to your doctor or nurse. Your doctor will discuss with you the possible risks and benefits of receiving FLUARIX TETRA.

**Before vaccination**

Tell your doctor if you or your child have an infection with a high temperature. Your doctor may decide to delay vaccination until the illness has passed.

A minor infection such as a cold is not usually a reason to delay vaccination, but talk to your doctor or nurse about this before being vaccinated.

• you are or think you may be pregnant or if you intend to become pregnant. Your doctor will discuss with you the possible risks and benefits of receiving FLUARIX TETRA during pregnancy.

• you are breast feeding. Your doctor will discuss the risks and benefits of vaccination, however the vaccine is not expected to cause problems for breast-fed babies.

• you or your child have had or have Guillain-Barré Syndrome (an inflammatory illness affecting nerves resulting in weakness of muscles).

• you or your child have any medical conditions, such as: − an immune deficiency condition, or − a bleeding disorder.

• you or your child have allergies to any medicines or substances, such as latex, dyes, foods or preservatives. • you or your child have received another vaccine, or are taking any prescription (e.g. theophylline, phenytoin, phenobarbitone, carbamazepine or warfarin) or OTC (over-the counter) medicines.

In particular mention if you or your child are taking medicines which suppress the immune system, such as steroids or cyclosporin.

Fainting can occur following, or even before, any needle injection, therefore tell the doctor or nurse if you or your child fainted with a previous injection.

**How much is given**

For adults and children over 6 months of age: 0.5 mL is given.

**How it is given**

FLUARIX TETRA is generally injected into the upper arm or upper thigh muscle.

**When it is given**

 For adults and older children FLUARIX TETRA is generally given as a single dose each year before the start of the influenza season, which is usually in winter.

• First dose: on an elected date

• Second dose: 4 weeks after the first (ONLY for children aged 6 months to less than 9 years receiving influenza vaccination for the first time)

**Side effects**

Tell your doctor, nurse or pharmacist as soon as possible if you or your child do not feel well during or after having had a dose of FLUARIX TETRA. All medicines and vaccines can have side effects. Sometimes they are serious; most of the time they are not. Some side effects may need medical treatment. Ask your doctor, nurse or pharmacist to answer any questions you may have. Most unwanted effects with FLUARIX TETRA are mild and usually clear up within a few days. These effects, as with other vaccines, generally occur around the injection site.

Tell your doctor if you notice any of the following that are troublesome or ongoing:

• redness, swelling, a hard lump, soreness, bruising or itching around the injection site

• pain at the injection site

• fever, chills, shivering, sweating, dizziness, headache, malaise (generally unwell)

• muscle aches and pains • joint pain

• loss of appetite, feeling sick, vomiting, diarrhoea, stomach pain

• irritability

• drowsiness

• fatigue

 • rash

The above list includes mild side effects.

Tell your doctor as soon as possible if you notice any of the following:

• transient swollen glands in the neck, armpit or groin

• painful swelling in the arms or legs

• vomiting

• Flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills

• weakness of muscles In very young children high fevers may result in convulsions (fits).

It is advisable to monitor young children for high fevers post (influenza) vaccination. There have been rare reports of Guillain-Barré Syndrome (an inflammatory illness affecting nerves resulting in weakness of muscles), however these events have not been definitely linked to the use of influenza vaccines. The above list includes serious side effects that may require medical attention. As with all vaccines given by injection there is a very small risk of serious allergic reaction.

Contact your doctor immediately or go to the casualty department of your nearest hospital if any of the following happens:

• swelling of limbs, face, eyes, inside of nose, mouth or throat

• shortness of breath, breathing or swallowing difficulties

• hives, itching (especially of the hands or feet), reddening of skin (especially around the ears), or severe skin reactions

• unusual tiredness or weakness that is sudden and severe. Allergy to FLUARIX TETRA is rare.

Any such severe reactions will usually occur within the first few hours of vaccination. Tell your doctor or pharmacist if you notice anything that is making you feel unwell during or after a dose of vaccine. Other side effects not listed above may also occur in some people. After being given FLUARIX TETRA

**Ingredients**

Each 0.5 mL dose of FLUARIX TETRA contains 15 micrograms of each of the four types of influenza virus fragments.

* A/Victoria/2570/2019 (H1N1)pdm09-like virus
* A/Hong Kong/2671/2019 (H3N2)-like virus
* B/Washington/02/2019-like (B/Victoria lineage) virus
* B/Phuket/3073/2013-like (B/Yamagata lineage) virus

The vaccine also contains:

• polysorbate 80

• octoxinol 10

• α-tocopheryl hydrogen succinate

• sodium chloride

• disodium phosphate dodecahydrate

• monobasic potassium phosphate

• potassium chloride

• magnesium chloride hexahydrate

• water for injections

• ovalbumin (≤0.05 micrograms)

• formaldehyde (≤5 micrograms)

• hydrocortisone (trace)

• gentamicin sulphate(trace)

• sodium deoxycholate (trace)

FLUARIX TETRA is not made with any human blood or blood products, or any other substances of human origin. The manufacture of this product includes exposure to bovine derived materials. No evidence exists that any case of vCJD (considered to be the human form of bovine spongiform encephalopathy) has resulted from the administration of any vaccine product.