

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PART III: PATIENT MEDICATION INFORMATION

YF-VAX[®] Yellow Fever Vaccine

Read this carefully before YF-VAX[®] is given to you or your child. This leaflet is a summary and will not tell you everything about this vaccine. Talk to your healthcare professional about your (or your child's) medical condition and treatment and ask if there is any new information about YF-VAX[®].

What is YF-VAX[®] used for?

YF-VAX[®] is a vaccine that is used to help prevent yellow fever. This vaccine may be given to adults and children 9 months of age and older who are:

- travelling to or living in countries and areas where yellow fever infection is officially reported or considered to exist.
- travelling to countries where yellow fever vaccination is required by law upon entry. Current information on the countries for which an International Certificate of Vaccination or Prophylaxis is required can be obtained from local public health departments or from the Public Health Agency of Canada's (PHAC) Travel Medicine Program web site.
- laboratory personnel who might be exposed to yellow fever virus or to concentrated preparations of the 17D vaccine strain.

The majority of persons who are vaccinated with YF-VAX[®] will produce enough antibodies to protect them from this disease. However, as with all vaccines, 100% protection cannot be guaranteed.

How does YF-VAX[®] work?

YF-VAX[®] causes your body to produce its own natural protection against the yellow fever virus. After you receive the vaccine, your body begins to make substances called antibodies. Antibodies help your body to fight disease. If a vaccinated person comes into contact with the yellow fever virus, the body is usually ready to destroy it.

What are the ingredients in YF-VAX[®]?

Medicinal Ingredients: 17D-204 strain of yellow fever vaccine virus which has been grown in chicken eggs.

Non-Medicinal Ingredients: Gelatin, Sodium Chloride, Sorbitol

YF-VAX[®] comes in the following dosage forms:

YF-VAX[®] is a powder and diluent for suspension that is mixed and injected subcutaneously (just under skin). A single dose is 0.5 mL

Do not use YF-VAX[®] if:

- You (or your child) are known to have a severe allergy to any ingredient in the vaccine, including eggs and chicken protein, or who have had a severe allergic reaction after receiving a vaccine that contained similar ingredients.
- You (or your child) have a weakened immune system because of cancer, HIV/AIDS or another disease that affects the immune system; treatment with drugs that affect the immune system such as steroids, cancer treatment with drugs or radiation.
- You (or your child) have had your thymus gland removed, or have a history of problems with the thymus such as myasthenia gravis or thymoma.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take YF-VAX[®]. Talk about any health conditions or problems you or your child may have, including if you or your child:

- **Have a high fever or serious illness.** Delay the vaccination until the person is better.
- **Have an allergy to any component of the vaccine or container.**
- **Are pregnant or breast-feeding.** It is important that you understand the risks and benefits of vaccination. YF-VAX[®] should be given to a pregnant or nursing woman only if it is clearly needed. Tell the person giving you the injection if you are pregnant or breast-feeding.
- **Are 60 years old and above.** Discuss with your doctor or nurse the risks and benefits of vaccination in the context of your risk for exposure to yellow fever virus at your destination.
- **Have fainted with a previous injection.** Fainting can occur following or even before any vaccination. Appropriate measures should be taken to prevent falling injury.

Tell your healthcare professional about all the medicines you or your child take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with YF-VAX[®]:

DO NOT mix YF-VAX[®] with other vaccines or medicinal products in the same syringe.

How to take YF-VAX[®]:

Usual Dose:

For persons 9 months of age and older - single dose of 0.5 mL.

The vaccination should be given subcutaneously (just under the skin).

People who continue to live in or travel to yellow-fever endemic areas should receive a booster dose of YF-VAX[®] after 10 years.

Yellow fever vaccine is only given at approved vaccination centres. After receiving vaccine, you should receive an International Certificate of Vaccination or Prophylaxis that has been validated by the vaccination centre.

Overdose:

If you think you (or your child) have been given too much YF-VAX[®], contact a health-care professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

Not applicable to this vaccine.

What are the possible side effects from using YF-VAX[®]?

These are not all the possible side effects you or your child may feel when taking YF-VAX[®]. If you or your child experience any side effects not listed here, contact your healthcare professional. Please also see Warnings and Precautions.

A vaccine, like any medicine, may cause serious problems, such as severe allergic reactions. The risk of YF-VAX[®] causing serious harm is extremely small. The small risks associated with YF-VAX[®] are much less than the risks of getting the disease against which it protects.

Tell your doctor or nurse as soon as possible if you do not feel well after receiving YF-VAX[®].

Some people who receive YF-VAX[®] may have mild side effects such as soreness, redness or swelling at the site of the injection. The side effects usually go away within a few days.

Serious side effects are very rare.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Suspected Side Effects**For the General Public:**

Should you (or your child) experience an adverse event following immunization, please report it to your doctor, nurse, or pharmacist.

Should you require information related to the management of the side effect, please contact your healthcare provider. The Public Health Agency of Canada, Health Canada and Sanofi Pasteur Limited cannot provide medical advice.

For Health Care Professionals:

If a patient experiences an adverse event following immunization, please complete the Adverse Events following Immunization (AEFI) Form appropriate for your province/territory (<http://www.phac-aspc.gc.ca/im/ae-fi-essi-form-eng.php>) and send it to your local Health Unit.

Storage:

Store the vaccine in a refrigerator at 2° to 8°C (35° to 46°F). **Do not freeze.**

After mixing, YF-VAX[®] must be stored in a refrigerator and used within 60 minutes.

Do not use vaccine after expiration date.

Keep out of reach and sight of children.

If you want more information about YF-VAX®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website; the Sanofi Canada website (www.sanofi.ca), or by calling the Sanofi Pasteur Limited Vaccine Information Service at 1-888-621-1146 (no charge) or 416-667-2779 (Toronto area).

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