

STAMARIL®

YELLOW FEVER VACCINE (LIVE)

Consumer Medicine Information

What is in this leaflet

Read all of this leaflet carefully before you or your child is vaccinated.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This vaccine has been prescribed for you or your child. Do not pass it on to others.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

- What STAMARIL is and what it is used for
- Before you or your child is given STAMARIL
- How STAMARIL is given
- Possible side effects
- Storing STAMARIL
- Further Information

What STAMARIL is and what it is used for

STAMARIL is a vaccine that provides protection against a serious infectious disease called yellow fever.

Yellow fever occurs in certain areas of the world and is spread to people through the bites of infected mosquitoes.

STAMARIL is given to people who:

- are travelling to, passing through or living in an area where yellow fever is present or may be present,
- are travelling to any country that requires an International Certificate of Vaccination for entry, this may depend on the countries previously visited during the same trip,
- may handle infectious materials such as laboratory workers.

To obtain a vaccination certificate against yellow fever it is necessary to be vaccinated in an approved vaccination centre by a qualified and trained health care professional so that an International Certificate of Vaccination can be issued. This certificate is valid from the 10th day after the vaccination.

Before you or your child is given STAMARIL

STAMARIL should not be given if you or your child:

- women who are pregnant or breast-feeding,
- children under 6 months of age,
- is allergic to eggs, chicken proteins or any other ingredient of STAMARIL,
- has experienced a serious reaction after an injection of a yellow fever vaccine,
- has an illness with a fever or acute infection. The vaccination will be postponed until you have recovered,

- has a poor or weakened immune system for any reason, such as illness or medical treatments (for example corticosteroids or chemotherapy),
- has a weakened immune system due to HIV infection. Your doctor will tell you if you can still receive STAMARIL based on your blood tests,
- is infected with HIV and has active symptoms due to the infection,
- has a history of problems with thymus gland or has had thymus gland removed for any reason.

Take special care with STAMARIL if:

- you are over 60 years old as you have an increased risk of certain types of severe but rare reactions to vaccines (including serious reactions that affect the brain and nerves, as well as vital organs). You will only be given the vaccine if the risk of infection with the virus is well established in countries where you are going to stay,
- your child is aged 6 to 9 months. STAMARIL may be given to children aged between 6 and 9 months only in special situations and on the basis of current official recommendations,
- you are infected with the HIV but do not present with any HIV infection related symptoms, your doctor will specify whether STAMARIL can be given based on your blood tests,
- your child is infected with the HIV (AIDS). The doctor may

need to perform specific exams and seek advice from a specialist before telling you whether your child may receive STAMARIL,

- you have bleeding disorders (such as haemophilia or a low level of platelets) or are taking medicines that reduce blood circulation. You can still receive STAMARIL provided that it is injected under the skin and not into a muscle,
- STAMARIL contains a small amount of sorbitol. The vaccine should not be given to people who have rare hereditary problems of fructose intolerance.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

If you have recently been receiving any treatment which may have weakened your immune system, vaccination against yellow fever should be postponed until your laboratory results show that your immune system has recovered. Your doctor will advise you when it is safe for you to be vaccinated.

Having other vaccines

STAMARIL can be given at the same time as vaccines against typhoid (those containing the Vi capsular polysaccharide).

In adults, STAMARIL can be given at the same time as IMOJEV (live attenuated vaccine against Japanese encephalitis).

Your doctor will advise you if STAMARIL can be given with another vaccine.

Pregnancy and breastfeeding

Tell your doctor or nurse if you are pregnant, think you might be pregnant or are breastfeeding. You should not receive STAMARIL unless this cannot be avoided. In case vaccination is needed you will need

to interrupt breastfeeding for at least 2 weeks following vaccination. Your doctor or nurse can advise you on whether it is essential that you are vaccinated while pregnant or breastfeeding.

How STAMARIL is given

STAMARIL is given as a single 0.5 mL dose injection by a doctor or nurse. It is usually injected under the skin but it can be given into a muscle.

It must not be injected into a blood vessel.

The injection should be given at least 10 days before being at risk of infection with yellow fever, because it takes 10 days for the vaccine to work and provide good protection against the yellow fever virus. The protection will last at least 10 years and may be a life-long protection. Some people may need to be re-vaccinated if they continue to be at risk for yellow fever virus infection.

Possible Side effects

Like all medicines, STAMARIL can cause side effects, although not everybody gets them.

Serious side effects

The following serious side effects have sometimes been reported:

Allergic reactions

- Rash, itching or hives on the skin.
- Swelling of the face, lips, tongue or other parts of the body.
- Difficulty swallowing or breathing.
- Loss of consciousness.

Reactions affecting the brain and nerves

These may occur within one month of the vaccination and have sometimes been fatal.

Symptoms include:

- High fever with headache and confusion.
- Extreme tiredness.
- Stiff neck.
- Inflammation of brain and nerve tissues.
- Fits.
- Loss of movement or feeling affecting certain parts or all of the body.

Serious reaction affecting vital organs

This may occur within 10 days of the vaccination and may have a fatal outcome. The reaction can resemble an infection with the yellow fever virus.

It generally begins with feeling tired, fever, headache, muscle pain and sometimes low blood pressure.

It may then go on to a severe muscle and liver disorders, drops in number of some types of blood cells resulting in unusual bruising or bleeding and increased risk of infections, and loss of normal functioning of the kidneys and lungs.

If you experience ANY of the above symptoms contact your doctor IMMEDIATELY.

Other side effects

Very common side effects (reported by more than 1 in 10 people)

- Injection site pain or discomfort
- Unusual weakness
- Muscle tenderness or weakness not caused by exercise
- Headache
- Fever, crying, irritability, drowsiness, vomiting, or appetite loss in children

Common side effects (reported by less than 1 in 10 people)

- Injection site redness, bruising, swelling or appearance of a hard lump
- Fever
- Painful joints
- Rash
- Feeling sick
- Vomiting
- Stomach pain

Uncommon side effects (reported by less than 1 in 100 people)

- Dizziness
- Itching

Rare side effects (reported by less than 1 in 1000 people)

- Diarrhoea
- Runny or blocked nose, sneezing, facial pressure or pain

Other possible side effects include:

- Swollen glands in the neck, armpit or groin
- Temporary lack of white blood cells, symptoms for which include frequent infections such as fever, severe chills, sore throat or mouth ulcers
- Itchy rash
- Fainting
- Tingling or numbness of the hands or feet
- Flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills

Storing STAMARIL

STAMARIL is usually stored in the doctor's surgery or clinic, or at the pharmacy. However, if you need to store STAMARIL

- Keep out of reach and sight of children.
- Keep STAMARIL in the original pack until it is time for it to be given.
- Keep it in the refrigerator, store at 2°C to 8°C. Do not freeze STAMARIL. Protect from light.

Do not use STAMARIL after the expiry date which is stated on the carton after EXP.

Do not have STAMARIL if the packaging is torn or shows signs of tampering.

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.

Further Information

What STAMARIL contains

Active substance:

Yellow fever virus (produced in specified pathogen-free chick embryos), 17D strain (live, attenuated): not less than 1000 IU

Other ingredients:

Lactose monohydrate, sorbitol, histidine hydrochloride, alanine, sodium chloride, potassium chloride, sodium phosphate dihydrate, monobasic potassium phosphate, calcium chloride dihydrate, magnesium sulfate heptahydrate and water for injections.

The manufacture of this product includes exposure to bovine 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.

Name and Address of Australian Sponsor

Australia:

sanofi-aventis australia pty ltd

12 – 24 Talavera Road

Macquarie Park NSW 2113

Australia

Tel: 1800 818 806

New Zealand:

sanofi-aventis new zealand limited

Level 8

56 Cawley St

Ellerslie

Auckland

New Zealand

Tel: 0800 283 684

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