# STAMARIL

**Powder and solvent for suspension for injection in pre-filled syringe**

## Yellow fever vaccine (Live)

**Read all of this leaflet carefully before you or your child are vaccinated because it contains important information for you.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your healthcare professional.
- This vaccine has been prescribed for you or your child only. Do not pass it on to others.
- If you get any side effects talk to your healthcare professional and tell them you received a yellow fever vaccine. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet:**



### 1. 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 man 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 occurs,
- 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 valid vaccination certificate against yellow fever, it is necessary to be vaccinated by a qualified and trained healthcare professional in an approved vaccination centre so that an International Certificate of Vaccination can be issued. This certificate is valid from 10 days after the first dose of vaccine. In some situations, when a booster is needed, the certificate (see section 3) is valid immediately after the injection.

### 2. WHAT YOU NEED TO KNOW BEFORE YOU OR YOUR CHILD USE STAMARIL

It is important to tell your healthcare professional if any of the points below apply to you or your child. If there is anything you do not understand, ask your healthcare professional to explain.

**Do not use STAMARIL if you or your child:**
- are allergic to:
  - the active substance, or
  - any of the other ingredients of this vaccine listed in section 6, or
  - eggs or chicken proteins,
- have experienced a severe allergic reaction after a previous dose of any yellow fever vaccine,
- is less than 6 months old,
- have a poor or weakened immune system for any reason, such as illness or medical treatments (for example high-dose corticoids, or any other medicine affecting the immune system or chemotherapy). If you don't know if your medicines may affect your immune system or that of your child, talk to your healthcare professional before administration of the vaccine,
- have a weakened immune system due to HIV infection. Your healthcare professional will tell you if you or your child can still receive STAMARIL based on the results of your blood tests,

are infected with HIV and have active symptoms due to the infection,
have a history of problems with your thymus gland or have had your thymus gland removed for any reason,
have an illness with a high or moderate temperature or an acute illness. The vaccination will be postponed until you or your child have recovered.

**Warnings and precautions**
Before you use STAMARIL, it is important that you do a risk assessment with a qualified healthcare professional, in order to determine if you need to receive the vaccine.
If you are over 60 years old or if your child is less than 9 months 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, see section 4). 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,
If 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 advice,
If you or your child are infected by the HIV virus but do not have active symptoms due to the infection. Your healthcare professional will advise if STAMARIL can be given based on the results of laboratory tests and specialist advice,
If you or your child have any bleeding disorders (such as haemophilia or a low level of platelets) or are taking any medicines that stop the blood clotting normally. You can still be given STAMARIL provided that it is injected under the skin and not into muscle (see section 3).
If you or your child are allergic to latex. The tip-caps of the prefilled syringes with no needle attached contain a natural latex derivative that could cause allergic reactions.
As with all vaccines, STAMARIL may not fully protect all persons who are vaccinated.
Fainting can occur following, or even before, any needle injection. Therefore tell your healthcare professional if you or your child fainted with a previous injection.

**Other medicines and STAMARIL**
Tell your healthcare professional if you are taking, have recently taken or might take any other medicines.
If you have recently had any treatment or medicine which may have weakened your immune system, the vaccination must be delayed 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.
STAMARIL can be given at the same time as measles vaccine or vaccines against typhoid fever (those containing the Vi capsular polysaccharide) and/or hepatitis A.
Vaccination with STAMARIL may lead to false positive results of blood tests for dengue or Japanese encephalitis. If you or your child have in the future such tests prescribed, please inform your doctor about this vaccination.

**Pregnancy and breast-feeding**
If you are pregnant, or breast-feeding, think you may be pregnant or are planning to have a baby, ask your healthcare professional for advice before being vaccinated.
You should not receive STAMARIL during pregnancy or breast-feeding unless this cannot be avoided. Moreover, it is recommended to not become pregnant in the month following vaccination with STAMARIL. Your healthcare professional can advise you on whether it is essential that you are vaccinated while pregnant or breast-feeding. If vaccination is needed, it is recommended to discontinue breast-feeding for at least 2 weeks after receiving STAMARIL.
If you receive the vaccine while pregnant or breast-feeding, consult your healthcare professional.

**STAMARIL contains sodium, potassium and sorbitol**
STAMARIL contains less than 1 mmol (23 mg) of sodium per dose, i.e. it is essentially "sodium-free" and less than 1 mmol (39 mg) of potassium per dose, i.e. it is essentially "potassium-free".
STAMARIL contains about 8 mg of sorbitol per dose.

### 3. HOW TO USE STAMARIL

**Posology**
STAMARIL is given as a single, 0.5 millilitre dose to adults and children from 6 months of age.
The first dose should be given at least 10 days before protection from yellow fever is needed. This is because it takes 10 days for the first dose of vaccine to work and provide good protection against the yellow fever virus. The protection provided by this dose is expected to last at least 10 years and may be life-long.
In some situations, a booster with one dose (0.5 millilitre) may be needed:
- if you or your child had an insufficient response to the first dose, and that you or your child are still at risk of yellow fever virus infection,
- or according to the official recommendations.

**How STAMARIL is given**
STAMARIL is given as an injection by a qualified and trained healthcare professional. It is usually injected just underneath the skin but it can be given into a muscle.
It must not be injected into a blood vessel.

**If you or your child use more STAMARIL than you should**
In some cases, more than the recommended dose was used.
In these cases, when side effects were reported, the information was in line with what is described in section 4.
If you have any further questions on the use of this vaccine, ask your healthcare professional.

### 4. POSSIBLE SIDE EFFECTS

Like all medicines, this vaccine 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 may include:*
High fever with headache and confusion.
Extreme tiredness.
Stiff neck.
Inflammation of brain and nerve tissues.
Fits.
Loss of movement or feeling in part or all of the body (for example, Guillain-Barré syndrome).
Change in personality.
*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 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 after vaccination, consult your doctor IMMEDIATELY telling them you received STAMARIL recently.**

**Other side effects**
*Very common (may affect more than 1 in 10 people):*
Headache.
Mild or moderate tiredness or weakness (asthenia).
Pain or discomfort at the injection site.
Muscle pains.
Fever (in children).
Vomiting (in children).
*Common (may affect up to 1 in 10 people):*
Fever (in adults).
Vomiting (in adults).
- Painful joints.
- Feeling sick (nausea).
- Reactions at the injection site: redness, bruising, swelling or appearance of a hard lump.

*Uncommon (may affect up to 1 in 100 people):*
- Dizziness.
- Stomach pains.
- A pimple (papule) at the injection site.

*Rare (may affect up to 1 in 1 000 people):*
- Diarrhoea.
- Runny, blocked or itchy nose (rhinitis).

*Not known (frequency cannot be estimated from the available data):*
Swollen glands (lymphadenopathy).
Numbness or pins and needles sensation (paraesthesia).
- Flu-like illness.

**Additional side effects in children**
*Very common (may affect more than 1 in 10 people):*
- Irritability, crying.
- Appetite loss.
- Drowsiness.

These side effects usually occurred within the 3 days following vaccination and lasted usually not more than 3 days. Most of these side effects were of mild intensity.

**Reporting of side effects**
If you get any side effects, talk to your healthcare professional. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

### 5. HOW TO STORE STAMARIL

Keep out of the sight and reach of children.
Do not use this vaccine after the expiry date which is stated on the carton 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 of powder and the syringe of solvent in the outer carton in order to protect from light.
Use immediately after reconstitution.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### 6. CONTENTS OF THE PACK AND OTHER INFORMATION

**What STAMARIL contains**
After reconstitution, for one dose (0.5 mL):
- The active substance is:
  Yellow fever virus[1], 17D-204 strain (live, attenuated) . . . . . .not less than 1000 IU
  [1] produced in specified pathogen-free chick embryos.
- The other ingredients are:
  Lactose, sorbitol, L-Histidine hydrochloride, L-Alanine, sodium chloride, potassium chloride, disodium phosphate dihydrate, potassium dihydrogen phosphate, calcium chloride, magnesium sulphate and water for injections.

**What STAMARIL is and contents of the pack**
STAMARIL is presented as a powder and solvent for suspension for injection (powder in vial (0.5 mL dose) + solvent in pre-filled syringe (0.5 mL dose) with or without needle(s)). Box of 1, 10 or 20.
After reconstitution the suspension is beige to pink beige, more or less opalescent.
Not all pack sizes may be marketed.

**Marketing authorisation holder**
**SANOFI PASTEUR** - 14 Espace Henry Vallée - 69007 LYON - FRANCE

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The following information is intended for healthcare professionals only:

Instructions for reconstitution:

Before use, the beige to orange beige powder is mixed with the clear colourless sodium chloride solvent provided in a syringe to make a beige to pink beige suspension, which is more or less opalescent.

For syringes without attached needle only: after removing the syringe tip cap, a needle should be firmly placed on the tip of the syringe and secured by rotating a quarter of a turn (90°).
The vaccine is reconstituted by adding the solvent provided in the pre-filled syringe to the vial. The vial is shaken and, after complete dissolution, the suspension obtained is withdrawn into the same syringe for injection.
Contact with disinfectants is to be avoided since they may inactivate the virus.
Use immediately after reconstitution.
Before administration, the reconstituted vaccine should be vigorously shaken.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.
See also section **3. HOW TO USE STAMARIL**.