Patient information leaflet for STAMARIL

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

STAMARIL, 1 000 IU/0,5 mL, powder and solvent for suspension for injection

Live, attenuated yellow fever virus strain 17D-204

Contains sugar (16 mg lactose per 0,5 mL) and sugar alcohol (8 mg sorbitol per 0,5 mL).

Read all of this leaflet carefully before STAMARIL is administered:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

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 in persons over 9 months of age.

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

STAMARIL is given to people who:

- Are travelling to, passing through or living in an area where there is a current or periodic risk of yellow fever transmission.
- 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 until 10 years after the first dose of vaccine. Certificates issued after a booster vaccination are valid immediately after the injection.

2. What you need to know before STAMARIL is administered

It is important to tell your doctor or nurse if any of the points below apply to the person receiving the vaccine. If there is anything you do not understand, ask your doctor or nurse to explain.

STAMARIL should not be administered if you or your child:

- Is hypersensitive (allergic) to the active ingredient, eggs, chicken proteins or any of the other ingredients of STAMARIL listed in section 6.
- Has experienced a serious allergic reaction after a previous dose of any yellow fever vaccine.
- Has an illness with a fever or acute infection. The vaccination will be postponed until you or your child has recovered.
- Has a poor or weakened immune system for any reason, such as illness or medical treatments (for example high doses of corticoids, or any other medicines that affect the immune system or chemotherapy). If you are unsure whether the medicine you or your child is taking may affect your or your child’s immune system, discuss this with your health care professional before STAMARIL is administered.

- Has a history of problems with your or your child's thymus gland or have had the thymus gland removed for any reason.
- Has a weakened immune system due to HIV infection. Your doctor will tell you if you or your child can still receive STAMARIL.
- Is infected with HIV and has active symptoms due to the infection.
- Is less than 6 months old.

Warnings and precautions

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 the 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.
- 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 or your child isHIV-infected but do not present with any HIV infection-related symptoms; your doctor will specify whether STAMARIL can be given based on you blood tests.
- You or your child is infected with HIV. The doctor may need to perform specific exams and seek advice from a specialist before telling you whether you or your child may receive STAMARIL.
- You or your child has 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 (see section 3).

As with all vaccines, STAMARIL may not fully protect all individuals who are vaccinated.

Fainting can occur following, or even before, any needle injection. Therefore, tell your health care professional if you or your child fainted with a previous injection.

Other medicines and STAMARIL:

Always tell your health care provider if you or your child are taking any other medicine. (This includes all complementary or traditional medicines.)

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

STAMARIL can be given at the same time as a measles vaccine or vaccines against typhoid (those containing the Vi capsular polysaccharide) and/or hepatitis A vaccines.

Vaccination with STAMARIL may lead to false positive results of blood tests for dengue or Japanese encephalitis. If in future such tests are prescribed for you or your child, please inform your doctor about this vaccination.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before the administration of STAMARIL.

You should not receive STAMARIL unless this cannot be avoided.

Your health care provider can advise you on whether it is essential that you are vaccinated while pregnant or breastfeeding.

It is recommended that you do not become pregnant within one month after receiving STAMARIL.

In case vaccination is needed, it is recommended to interrupt breastfeeding for at least 2 weeks after you have received STAMARIL.

STAMARIL contains sodium, potassium and sorbitol:

STAMARIL contains less than 1 mmoL sodium (23 mg) per dose, that is to say essentially sodium free and less than 1 mmoL potassium (39 mg) per dose, that is to say essentially potassium free.

STAMARIL contains 8 mg sorbitol per 0,5 mL. STAMARIL should not be given to people who

have fructose intolerance.

3. How STAMARIL will be administered

STAMARIL is given as an injection by a qualified and trained health care professional. It is usually injected just underneath the skin but it can be given into a muscle if that is in the applicable official recommendation of the country in which you live.

It must not be injected into a blood vessel.

Dosage

STAMARIL is given as a single 0,5 mL dose to adults and children from 9 months of age. In specific circumstances STAMARIL is given to children from 6 months up to 9 months.

The first dose should be given at least 10 days before being at risk of infection with yellow fever because it takes 10 days for the first dose of the vaccine to work and provide good protection against the yellow fever virus. The protection provided by this dose will last at least 10 years and may be life-long.

A booster dose, 0,5 mL is recommended every 10 years if you or your child is still thought to be at risk of infection with yellow fever (e.g. you still travel to or are living in areas where yellow fever can be caught or could be infected through your work).

A booster with one dose (0,5 mL) may also be needed:

- If you or your child had an insufficient response to the first dose
- Or depending on official recommendations.

If you have any further questions on the use of this vaccine, ask your health care professional.

If more STAMARIL is administered to you or your child than should be

Since a health care provider will administer STAMARIL, he/she will control the dosage. However, in the event of overdosage your health care provider will manage the overdosage.

When side effects were reported in cases where more than the recommended dose was used, they were in line with those described in section 4.

4. Possible side effects

STAMARIL can have side effects. Not all side effects reported for STAMARIL are included in this leaflet. Should your or your child's general health worsen or if you or your child experience any untoward effects after administration of STAMARIL, please consult your health care provider for advice.

If any of the following happens after administration of STAMARIL, tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash, itching or hives on the skin.
- Fainting (loss of consciousness).

These are all very serious side effects. If you or your child has them, you or your child may have had a serious reaction to STAMARIL. You or your child may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

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 parts of the body.
- Personality changes.

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. These are all serious side effects. You or your child may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Problems around the injection site (such as redness, bruising, pain or discomfort, swelling or appearance of a hard lump).
- Headache.
- Mild or moderate tiredness or weakness.
- Nausea (feeling sick), vomiting (being sick), muscle pains, fever and weakness.
- Painful joints.
- Irritability, appetite loss and crying (only in children).
- Drowsiness (only in children).

Less frequent side effects:

- Stomach pains.
- Diarrhoea.
- Runny, blocked or itchy nose (rhinitis).
- Dizziness.
- A pimple (papule) at the injection site.

Side effects that occur with unknown frequency:

- Swollen glands.
- Flu-like illness.

If any of the side effects gets serious, or if you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of STAMARIL.
Side effects can be reported directly to Sanofi’s Pharmacovigilance Unit at za.drugsafety@sanofi.com (email) or 011 256 3700 (tel).

5. How to store STAMARIL

- Store all medicine out of reach of children.
- Do not use STAMARIL after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
- Store (in a refrigerator) between 2 °C and 8 °C.
- Do not freeze.
- Keep the vial and syringe in the outer carton in order to protect them from light.
- Use immediately after reconstitution.

6. Contents of the pack and other information

What STAMARIL contains

Each immunising dose (0,5 mL) contains at least 1 000 IU of live, attenuated yellow fever virus (Strain 17D-204) produced in specified pathogen free chick embryos.

The other ingredients are calcium chloride, disodium phosphate dihydrate, lactose, L-alanine, L-

histidine hydrochloride, magnesium sulphate, potassium dihydrogen phosphate, potassium chloride, sodium chloride (0,4 %), sorbitol (E420), water for injections.

What STAMARIL looks like and contents of the pack

Freeze-dried vaccine: Beige to orange beige and homogeneous.

Solvent: Clear and colourless.

After reconstitution the suspension is beige to pink beige, more or less opalescent.

Freeze-dried vaccine in a Type I glass vial with a chlorobutyl stopper and a purple flip-off cap.

0,5 mL of solvent in a Type I glass pre-filled syringe with a bromobutyl or chlorobutyl plunger-stopper, with a 25 G 16 mm stainless steel needle and needle-shield attached.

Pack size: singles.

Holder of certificate of registration

sanofi-aventis south africa (pty) ltd

2 Bond Street

Midrand 1685

South Africa

011 256 3700

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SADC REGISTRATION DETAILS:

Botswana: S2

Reg. No.: BOT0300559

Namibia: NS2

Reg. No.: 04/30.1/1778

Zimbabwe: PP

Reg. No.: 99/18.2/3637