PRODUCT INFORMATION

STAMARIL, powder and solvent for suspension for injection in prefilled syringe

Yellow fever vaccine (Live)

ENGLISH TRANSLATION

French MA dates	**Modified sections in Annex I** *(as indicated in the ANSM document)*
25 November 2009	Full document
07 September 2010	6.5, 8
13 December 2010	4.4, 4.6
7 January 2014	2, 4.8, 6.5

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

STAMARIL, powder and solvent for suspension for injection in prefilled syringe,

Yellow fever vaccine (Live)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

After reconstitution, 1 dose (0.5 ml) contains:

Yellow fever virus[1], 17D-204 strain (live, attenuated) ..... not less than 1000 IU

[1] produced in specified pathogen-free chick embryos

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder and solvent for suspension for injection.

Before reconstitution, the powder is beige to orange beige; the solvent is clear and colourless.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

STAMARIL is indicated for active immunization against yellow fever in persons:

- travelling to, passing through or living in an endemic area,
- travelling to any country that requires an International Certificate of Vaccination for entry (which may or may not depend on the previous itinerary),
- handling potentially infectious materials (e.g. laboratory personnel).

See sections 4.2, 4.3 and 4.4 regarding the minimum age for vaccination of children under special circumstances and guidance for vaccination of other specific patient populations.

In order to comply with vaccine regulations and to be officially recognised, yellow fever vaccines must be administered in an approved World Health Organization (WHO) vaccination centre and registered on an International Certificate of Vaccination. This certificate is valid for 10 years from the 10th day after vaccination and immediately after re-vaccination.

4.2 Posology and method of administration

Posology

Primary vaccination

Adults and children aged 9 months and over: a single dose of 0.5 ml of reconstituted vaccine.

Children under 9 months of age: the vaccine must not be given to children less than 6 months old (see section 4.3). Vaccination against yellow fever is not usually recommended in children aged from 6 months up to 9 months except in specific circumstances and in accordance with available official recommendations (see section 4.4), in which case the dose is the same as in older children and adults.

The vaccine should be given at least 10 days before entering an endemic area since protective immunity may not be achieved until at least this time has elapsed.

Elderly

The dose is the same as for adults. However due to a higher risk of yellow fever vaccine-associated severe and potentially fatal disease in persons from 60 years of age, the vaccine should only be given

when it is considered that there is a considerable and unavoidable risk of acquiring yellow fever infection (see sections 4.4 and 4.8).

Re-vaccination

Re-vaccination with one dose of 0.5 ml is recommended every 10 years in persons considered to be at risk of exposure. International Health Regulations require re-vaccination, using the same dose as for primary vaccination, at intervals of 10 years in order to retain a valid certificate.

Method of administration

It is preferable that the vaccine is injected by the subcutaneous route.

Intramuscular injection may be performed if this is in accordance with applicable official recommendations.

For intramuscular use the recommended injection sites are the anterolateral aspect of the thigh in the infants and toddlers (6 months up to 2 years of age) and the deltoid muscle in older children and adults.

DO NOT INJECT INTRAVASCULARLY.

See section 6.6. for instructions on reconstitution.

4.3 Contraindications

- Hypersensitivity reaction to eggs, chicken proteins or to any component of STAMARIL.
- Serious hypersensitivity reactions (*e.g.*, anaphylaxis) after a previous dose of any yellow fever vaccine.
- Immunosuppression, whether congenital, idiopathic or as a result of treatment with systemic steroids (greater than the standard dose of topical or inhaled steroids), radiotherapy or cytotoxic drugs.
- History of thymus dysfunction (including thymoma, thymectomy).
- Symptomatic HIV infection.
- Asymptomatic HIV infection when accompanied by evidence of impaired immune function (see section 4.4).
- Age less than 6 months (see sections 4.2 and 4.4).
- Current severe febrile illness.

4.4 Special warnings and precautions for use

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of anaphylaxis or other severe hypersensitivity reaction following administration of the vaccine.

STAMARIL should be administered only to persons who are/will be at risk of infection with yellow fever virus or who must be vaccinated to comply with international health regulations. Before considering administration of yellow fever vaccine, care should be taken to identify those who might be at increased risk of adverse reactions following vaccination (see section 4.3 and below).

Yellow fever vaccine-associated neurotropic disease (YEL-AND)

Very rarely, yellow fever vaccine-associated neurotropic disease (YEL-AND) has been reported following vaccination, with sequelae or with fatal outcome in some cases (see section 4.8). Clinical features have appeared within one month of vaccination and include high fever with headache that may progress to include one or more of the following: confusion, encephalitis/encephalopathy, meningitis, focal neurological deficits, or Guillain Barré syndrome. To date, those affected have been primary vaccinees. The risk appears to be higher in those aged over 60 years, although cases have been also reported in younger persons or following transmission from nursing mothers to the infants.

Yellow fever vaccine-associated viscerotropic disease (YEL-AVD)

Very rarely, yellow fever vaccine-associated viscerotropic disease (YEL-AVD) resembling fulminant infection by wild-type virus has been reported following vaccination (see section 4.8). The clinical presentation may include fever, fatigue, myalgia, headache, hypotension, progressing to one or more of metabolic acidosis, muscle and liver cytolysis, lymphocytopenia and thrombocytopenia, renal failure and respiratory failure. The mortality rate has been around 60%. To date, all cases of YEL-AVD have been in primary vaccinees with onset within 10 days of vaccination. The risk appears to be higher in

those aged over 60 years although cases have also been reported in younger persons. Disease of the thymus gland has also been recognised as a potential risk factor (see section 4.3 and section 4.8).

Immunosuppressed persons

STAMARIL must not be administered to immunosuppressed persons (see section 4.3).

If the immunosuppression is temporary, vaccination should be delayed until the immune function has recovered. In patients who have received systemic corticosteroids for 14 days or more, it is advisable to delay vaccination until at least one month after completing the course.

HIV infection

STAMARIL must not be administered to persons with symptomatic HIV infection or with asymptomatic HIV infection when accompanied by evidence of impaired immune function (see section 4.3). However, there are insufficient data at present to determine the immunological parameters that might differentiate persons who could be safely vaccinated and who might mount a protective immune response from those in whom vaccination could be both hazardous and ineffective. Therefore, if an asymptomatic HIV-infected person cannot avoid travel to an endemic area available official guidance should be taken into account when considering the potential risks and benefits of vaccination.

Children born to HIV positive mothers

Children aged at least 6 months (see sections 4.2 and 4.3 and below) may be vaccinated if it is confirmed that they are not infected with HIV.

HIV infected children aged at least 6 months who are potentially in need of protection against yellow fever should be referred to a specialist paediatric team for advice on whether or not to vaccinate.

Age

Children aged 6 to 9 months

STAMARIL must not be administered to children before the age of 6 months (see section 4.3). Children aged from 6 months up to 9 months should only be vaccinated under special circumstances (e.g. during major outbreaks) and on the basis of current official advice.

Persons aged 60 years and older

Some serious and potentially fatal adverse reactions (including systemic and neurological reactions persisting more than 48 hours, YEL-AVD and YEL-AND) appear to occur at higher frequencies after the age of 60 years. Therefore, the vaccine should only be given to those who have a considerable risk of acquiring yellow fever (see above and section 4.8).

Because intramuscular injection can cause injection site haematoma, STAMARIL should not be given by the intramuscular route to persons with any bleeding disorder, such as haemophilia or thrombocytopenia, or to persons on anticoagulant therapy. The subcutaneous route of administration should be used instead.

Patients with rare hereditary problems of fructose intolerance should not take this vaccine.

Transmission

There are very few reports suggesting that transmission of Yellow Fever vaccine virus may occur from nursing mothers, who received Yellow Fever vaccine postpartum, to the infant. Following transmission the infants may develop yellow fever vaccine associated neurotropic disease (YEL-AND) from which the infants recover (see section 4.6).

4.5 Interaction with other medicinal products and other forms of interaction

STAMARIL must not be mixed with any other vaccine or medicinal product in the same syringe.

If there is a need to administer another injectable vaccine(s) at the same time as STAMARIL each vaccine should be injected into a separate site (and preferably a separate limb).

STAMARIL may be administered at the same time as measles vaccine if this is in accordance with official recommendations.

STAMARIL may be administered at the same time as vaccines containing typhoid Vi capsular polysaccharide and/or inactivated hepatitis A virus.

STAMARIL must not be administered to persons who are receiving immunosuppressant therapy (*e.g.*, cytotoxic agents, systemic steroids, greater than standard dose of topical or inhaled steroids or other agents). See section 4.3.

4.6 Pregnancy and lactation

Pregnancy

No animal reproduction studies have been conducted with STAMARIL and the potential risk for humans is unknown. Data on a limited number of exposed pregnancies indicate no adverse effects of STAMARIL on pregnancy or the health of the fetus/newborn child. Nevertheless, STAMARIL should be given to pregnant women only when clearly needed and only after careful consideration of the potential risks and benefits.

Lactation

As there is a probable risk of transmission of the vaccine virus strain to the infants from breast-feeding mothers, STAMARIL should not be given to nursing mothers unless when clearly needed such as during an outbreak control, and following an assessment of the risks and benefits (see section 4.4).

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive or use machines have been performed.

4.8 Undesirable effects

Data from clinical studies

Across clinical studies, the most common adverse reactions occurring after vaccine administration were local reactions, reported in approximately 16% of subjects.

The following adverse events are from one clinical study in which 106 healthy adult subjects received STAMARIL.

The adverse events are ranked under headings of frequency, using the following convention:

- Very common: ≥ 1/10
- Common: ≥ 1/100 and < 1/10
- Uncommon: ≥ 1/1000 and < 1/100

Nervous system disorders

Very common: headache.

Gastro-intestinal system disorders

Common: nausea, diarrhoea, vomiting.

Uncommon: abdominal pain.

Musculo-skeletal and connective tissue disorders

Common: myalgia.

Uncommon: arthralgia.

General disorders and administration site conditions

Very common: local reactions (including pain, redness, haematoma, induration, swelling).

Common: pyrexia, asthenia.

Data from post-marketing experience

The following additional adverse events have been reported during post marketing experience with STAMARIL. They are based on spontaneous reporting therefore the frequencies are unknown.

Blood and lymphatic system disorders

Lymphadenopathy.

Immune system disorders

Anaphylaxis, angioedema.

Nervous system disorders

Cases of neurotropic disease (known as YEL-AND), some of which resulted in death, have been reported following yellow fever vaccination (see section 4.4). The neurotropic disease may manifest as high fever with headache that may progress to confusion, lethargy, encephalitis, encephalopathy or meningitis (see section 4.4).

Other neurological signs and symptoms have been reported and include convulsion, Guillain-Barré syndrome and focal neurological deficits.

Skin and subcutaneous tissue disorders

Rash, urticaria.

General disorders and administration site conditions

Cases of viscerotropic disease (known as YEL-AVD and formerly described as "Febrile Multiple Organ-System Failure"), some of which resulted in death, have been reported following yellow fever vaccination, (see section 4.4). The viscerotropic disease may manifest as fever, fatigue, myalgia, headache and hypotension progressing to metabolic acidosis, muscle and liver cytolysis, lymphocytopenia and thrombocytopenia, and renal or respiratory failure.

Additional information on special population

Congenital or acquired immunodeficiency has been identified as a risk factor for neurotropic disease (see sections 4.3 and 4.4).

Age of more than 60 years has been identified as a risk factor for neurotropic and viscerotropic diseases associated with yellow fever vaccination (see section 4.4). A medical history of thymic disease has also been identified as a risk factor for viscerotropic disease (see sections 4.3 and 4.4).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system: « Agence nationale de sécurité du médicament et des produits de santé (Ansm) et réseau des Centres Régionaux de Pharmacovigilance » - Internet website: www.ansm.sante.fr.

4.9 Overdose

No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Yellow Fever Vaccine (Live), ATC code: J07B-L1.

STAMARIL is a live attenuated yellow fever virus vaccine. As with other live attenuated viral vaccines, there is a sub-clinical infection in healthy recipients that results in the production of specific B and T cells and the appearance of specific circulating antibody.

Protective immunity appears from about 10 days after injection. Although International Health Regulations require re-vaccination at intervals of 10 years in order to retain a valid certificate, some degree of immunity likely persists for more than 10 years.

5.2 Pharmacokinetic properties

No pharmacokinetic studies have been performed.

5.3 Preclinical safety data

Pre-clinical data reveal no special hazard for humans.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Powder:

Lactose
Sorbitol E420
L-histidine hydrochloride
L-alanine
Sodium chloride
Potassium chloride
Disodium phosphate
Monopotassium phosphate
Calcium chloride
Magnesium sulphate

Solvent:

Sodium chloride
Water for injections

6.2 Incompatibilities

In the absence of compatibility studies, this vaccine must not be mixed with other medicinal products.

6.3 Shelf life

3 years.

After reconstitution, the medicinal product must be used immediately.

6.4 Special precautions for storage

Store in a refrigerator (2°C – 8°C). Do not freeze. Keep the vial in the outer carton in order to protect from light.

For storage conditions of the reconstituted medicinal product, see section 6.3.

6.5 Nature and contents of container

Powder in vial (type I glass), with a stopper (chlorobutyl) and a flip-off cap (aluminium) + 0.5 mL of solvent in prefilled syringe (type I glass), with a plunger-stopper (halobutyl), with an attached needle and a needle-shield (natural rubber or polyisoprene) – box of 1, 10 or 20.

Powder in vial (type I glass), with a stopper (chlorobutyl) and a flip-off cap (aluminium) + 0.5 mL of solvent in prefilled syringe (type I glass), with a plunger-stopper (halobutyl) and a tip cap (chlorobromobutyl or butadiene styrene) – box of 1 or 10.

Powder in vial (type I glass), with a stopper (chlorobutyl) and a flip-off cap (aluminium) + 0.5 mL of solvent in prefilled syringe (type I glass), with a plunger-stopper (halobutyl) and a tip cap (chlorobromobutyl or butadiene styrene) with 1 or 2 separate needles provided in the blister – box of 1 or 10.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

For syringe without attached needle only: after removing the syringe tip cap, the needle should be firmly placed on the tip of the syringe and secured by rotating a quarter of a turn (90°).

The powder is reconstituted by adding the solvent provided in the prefilled syringe to the vial. The vial is shaken and, after complete dissolution, the suspension obtained is withdrawn into this same syringe for injection.

Before administration, the reconstituted vaccine should be shaken vigorously.

Use immediately after reconstitution.

After reconstitution the suspension is beige to pink beige.

Contact with disinfectants is to be avoided since they may inactivate the virus.

Any unused product or waste material should be disposed of, preferably by heat inactivation or incineration, in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

SANOFI PASTEUR
2, AVENUE PONT PASTEUR
69007 LYON
FRANCE

8. MARKETING AUTHORISATION NUMBER(S)

- 350 810-1 or 34009 350 810 1 8: powder in vial (type I glass), with a stopper (chlorobutyl) + 0.5 mL of solvent in prefilled syringe (type I glass), with a plunger-stopper (halobutyl), with an attached needle and a needle shield - box of 1.
- 350 811-8 or 34009 350 811 8 6: powder in vial (type I glass), with a stopper (chlorobutyl) + 0.5 mL of solvent in prefilled syringe (type I glass), with a plunger-stopper (halobutyl), with an attached needle and a needle shield - box of 10.
- 350 812-4 or 34009 350 812 4 7: powder in vial (type I glass), with a stopper (chlorobutyl) + 0.5 mL of solvent in prefilled syringe (type I glass), with a plunger-stopper (halobutyl), with an attached needle and a needle shield - box of 20.
- 369 931-9 or 34009 369 931 9 8: powder in vial (type I glass), with a stopper (chlorobutyl) + 0.5 mL of solvent in prefilled syringe (type I glass), with a plunger-stopper (halobutyl) and a tip-cap (chlorobromobutyl or butadiene styrene) - box of 1.
- 369 932-5 or 34009 369 932 5 9: Powder in vial (type I glass), with a stopper (chlorobutyl) + 0.5 mL of solvent in prefilled syringe (type I glass), with a plunger-stopper (halobutyl) and a tip-cap (chlorobromobutyl or butadiene styrene) - box of 10.
- 369 933-1 or 34009 369 933 1 0: powder in vial (type I glass), with a stopper (chlorobutyl) + 0.5 mL of solvent in prefilled syringe (type I glass), with a plunger-stopper (halobutyl) and a tip cap (chlorobromobutyl or butadiene styrene), with 2 separate needles - box of 1.
- 369 934-8 or 34009 369 934 8 8: powder in vial (type I glass), with a stopper (chlorobutyl) + 0.5 mL of solvent in prefilled syringe (type I glass), with a plunger-stopper (halobutyl) and a tip cap (chlorobromobutyl or butadiene styrene), with 2 separate needles - box of 10.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

- Date of first authorisation: 27 January 1986.
- Date of renewal of the authorisation: unlimited, starting from 26 June 2007.

10. DATE OF REVISION OF THE TEXT

07 January 2014.

11. DOSIMETRY

Not applicable.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

GENERAL CLASSIFICATION FOR SUPPLY

Reserved for vaccination centres authorised to perform yellow fever vaccination.

ANNEX II

A. MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

A.1. Name and address of the manufacturer(s) of the biological active substance(s)

SANOFI PASTEUR
PARC INDUSTRIEL D'INCARVILLE
B.P. 101
27101 VAL DE REUIL CEDEX
FRANCE

A.2. Name and address of the manufacturer(s) responsible for batch release

SANOFI PASTEUR
2, AVENUE PONT PASTEUR
69007 LYON
FRANCE

OR

SANOFI PASTEUR
1225 BUDAPEST
CAMPONA U.L. (HARBOR PARK)
HUNGARY

B. CONDITIONS OF THE MARKETING AUTHORISATION

B.1. Conditions or restrictions regarding supply and use imposed on the marketing authorisation holder

Reserved for vaccination centres authorised to perform yellow fever vaccination.

B.2. Conditions or restrictions with regard to the safe and effective use of the medicinal product

Not applicable.

B.3. Other conditions

Not applicable.

C. SPECIFIC OBLIGATIONS TO BE FULFILLED BY THE MARKETING AUTHORISATION HOLDER

Not applicable.

D. QUALITATIVE AND QUANTITATIVE COMPOSITION IN EXCIPIENTS

One dose (0.5 ml) of vaccine contains:

Lactose	15.950 mg
Sorbitol E420	7.975 mg
L-histidine hydrochloride	0.833 mg
L-alanine	0.362 mg
Sodium chloride	1.630 mg
Potassium chloride	0.054 mg
Disodium phosphate	0.298 mg
Monopotassium phosphate	0.063 mg
Calcium chloride	0.039 mg
Magnesium sulphate	0.029 mg

One dose (0.5 ml) of reconstitution solvent contains:

Sodium chloride	2.0 mg
Water for injections	q.s. 0.5 ml

ANNEX IIIA

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

NATURE/TYPE Outer packaging or immediate packaging

0.5 ml vial packaging / syringe with attached needle. Pack size of 1, 10, 20.

0.5 ml vial packaging / syringe with 1 or 2 separate needles. Pack size of 1, 10.

0.5 ml vial packaging / syringe. Pack size of 1, 10.

1. NAME OF THE MEDICINAL PRODUCT

STAMARIL, powder and solvent for suspension for injection in prefilled syringe,

Yellow fever vaccine (Live)

2. STATEMENT OF ACTIVE SUBSTANCES

After reconstitution, one dose (0.5 ml) contains:

Yellow fever virus[1], 17D-204 strain (live, attenuated) ..... not less than 1000 IU

[1] produced in specified pathogen-free chick embryos

3. LIST OF EXCIPIENTS

Powder: lactose, sorbitol, L-histidine hydrochloride, L-alanine, sodium chloride, potassium chloride, disodium phosphate, monopotassium phosphate, calcium chloride, magnesium sulphate.

Solvent: sodium chloride (0.4%), water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

Powder and solvent for suspension for injection in prefilled syringe (powder in vial + 0.5 ml of solvent in prefilled syringe <with attached needle> <with> <1> <2> <separate needle(s)>). Pack size of <1> <10> <20>.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous or intramuscular use.
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Not applicable.

8. EXPIRY DATE

EXP {MM/AAAA}

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2°C – 8°C). Do not freeze. Keep the vial in the outer carton in order to protect from light.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Not applicable.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Holder

SANOFI PASTEUR
2, AVENUE PONT PASTEUR
69007 LYON
FRANCE

Distributor

SANOFI PASTEUR MSD SNC
8, RUE JONAS SALK
69007 LYON
FRANCE

Manufacturer

Not applicable.

12. MARKETING AUTHORISATION NUMBER(S)

Number of Authorized Medicinal Product:

13. BATCH NUMBER

Batch {number}

14. GENERAL CLASSIFICATION FOR SUPPLY

Reserved for vaccination centres authorised to perform yellow fever vaccination.

15. INSTRUCTIONS ON USE

Not applicable.

16. INFORMATION IN BRAILLE

In accordance with local requirements.

PICTOGRAM TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING

Not applicable.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

NATURE/TYPE Blisters / Strips

Not applicable.

1. NAME OF THE MEDICINAL PRODUCT

Not applicable.

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Holder

Not applicable.

Distributor

Not applicable.

3. EXPIRY DATE

Not applicable.

4. BATCH NUMBER

Not applicable.

5. OTHER

Not applicable.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

NATURE/TYPE Small immediate packaging units

Single vial of powder / prefilled syringe of solvent 4 mg/ml (0.4%)

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

STAMARIL, powder

Yellow fever vaccine (Live)

<Solvent for STAMARIL reconstitution >

<SC or IM after reconstitution>

2. METHOD OF ADMINISTRATION

3. EXPIRY DATE

EXP {MM/AAAA}

4. BATCH NUMBER

Batch {number}

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

<1 dose>

<1 dose (0.5 ml) of sodium chloride solution 0.4%

6. OTHER

Sanofi Pasteur MSD SNC

ANNEX IIIB

PACKAGE LEAFLET: INFORMATION FOR THE USER

Name of the medicinal product

STAMARIL, powder and solvent for suspension for injection in prefilled syringe,

Yellow fever vaccine (Live)

Box

Read all of this leaflet carefully before you or your child are 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, see section 4.

Summary package leaflet

In this leaflet:

1. WHAT STAMARIL IS AND WHAT IT IS USED FOR

Pharmacotherapeutic group

Not applicable.

Therapeutic indications

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 vaccination certificate against yellow fever it is necessary to be vaccinated in an approved vaccination centre so that an International Certificate of Vaccination can be issued. This certificate is valid from the 10th day and until 10 years after the first dose of vaccine. Certificates issued after a booster vaccination (see section 3 below) are valid immediately after the injection.

2. BEFORE YOU USE STAMARIL

List of information necessary before taking the medicinal product

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.

Contraindications

STAMARIL should not be given if you or your child:

- are allergic to eggs, chicken proteins or any other ingredient of STAMARIL,
- have experienced a serious reaction after an injection of a yellow fever vaccine,
- have a poor or weakened immune system for any reason, such as illness or medical treatments (for example corticoids or chemotherapy),
- have a weakened immune system due to HIV infection. Your doctor will tell you if you can still receive STAMARIL based on 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 fever or acute infection. The vaccination will be postponed until you have recovered,
- **are less than 6 months old.**

Precautions for use; special warnings

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, 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 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 (see section 3).

Interactions with other medicinal products

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.

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.

Interactions with food and drink

Not applicable.

Interaction with phytotherapy or alternative therapy products

Not applicable.

Use during pregnancy and breast-feeding

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. Your doctor or nurse can advise you on whether it is essential that you are vaccinated while pregnant or breastfeeding.

Athletes

Not applicable.

Effects on ability to drive or use machines

Not applicable.

List of excipients with recognised effect

Important information about some of the ingredients of STAMARIL:

STAMARIL contains a small amount of sorbitol. The vaccine should not be given to people who have fructose intolerance.

3. HOW TO USE STAMARIL

Instructions for proper use

STAMARIL is given as an injection by a doctor or nurse. It is usually injected just underneath the skin but it can be given into a muscle if that is in the applicable official recommendation for the country in which you live.

It must not be injected into a blood vessel.

Dosage, Method and/or route(s) of administration, Frequency of administration and Duration of treatment

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 being at risk of infection with yellow fever, 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 will last 10 years.

A booster dose (0.5 millilitre) is recommended every 10 years if you are 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).

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

Symptoms and instructions in the case of overdose

Not applicable.

Instructions in the case of missing doses

Not applicable.

Risk of withdrawal syndrome

Not applicable.

4. POSSIBLE SIDE EFFECTS

Description of 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)

Problems around the injection site (such as rednesss, bruising, pain or discomfort, swelling or appearance of a hard lump) and headache.

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

Feeling or being sick, diarrhoea, muscle pains, fever and weakness.

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

Painful joints and stomach pains.

Other possible side effects include:

Swollen glands.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: « Agence nationale de sécurité du médicament et des produits de santé (Ansm) et réseau des Centres Régionaux de Pharmacovigilance » - Internet website: www.ansm.sante.fr. 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 reach and sight of children.

Expiry date

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.

Storage conditions

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 from light.

Use immediately after reconstitution.

Where appropriate, warning against certain visible signs of deterioration

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.

6. FURTHER INFORMATION

Full statement of the active substances and excipients

What STAMARIL contains

Active substance:

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, monopotassium phosphate, calcium chloride, magnesium sulphate and water for injections.

Pharmaceutical form and contents

What STAMARIL looks like and contents of the pack

STAMARIL is presented as a powder and solvent for suspension for injection (powder in a vial (0.5 ml dose) + solvent in a prefilled syringe (0.5 ml dose) with or without needle). Pack size of 1, 10 or 20.

After reconstitution the suspension is beige to pink beige.

Not all pack sizes or presentations may be marketed.

Name and address of the marketing authorisation holder and of the manufacturing authorisation holder responsible for batch release, if different

Holder

SANOFI PASTEUR
2, AVENUE PONT PASTEUR
69007 LYON
FRANCE

Distributor

SANOFI PASTEUR MSD SNC
8, RUE JONAS SALK
69007 LYON
FRANCE

Manufacturer

SANOFI PASTEUR
2, AVENUE PONT PASTEUR
69007 LYON
FRANCE

OR

SANOFI PASTEUR
1225 BUDAPEST
CAMPONA U.L. (HARBOR PARK)
HUNGARY

Names of the medicinal product in the Member States of the European Economic Area

In accordance with official recommendations.

Date of approval of the package leaflet

This leaflet was last approved in 01/2014.

Marketing authorisation under exceptional circumstances

Not applicable.

Internet information

Detailed information on this medicinal product is available on the website of Ansm (France): www.ansm.sante.fr.

Information intended for healthcare professionals

The following information is intended for medical or healthcare professionals only:

Instruction 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.
For syringe without attached needle only: after removing the syringe tip cap, the needle should be firmly placed on the tip of the syringe and secured by rotating a quarter of a turn (90°).
The powder 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 this same syringe for injection.

Contact with disinfectants is to be avoided so as not to inactivate the virus.

Use immediately after reconstitution.

Any unused product or waste material should be disposed of, preferably by heat inactivation or incineration, in accordance with local requirements.

See also section 3. HOW TO USE STAMARIL.

Other

Not applicable.