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French National Agency for Medicines
and Health Products Safety

REPUBLIC OF FRANCE

References	
NL	CIS
NL14156	6 210 296 2

Decision

granting a modification to the marketing authorisation for the proprietary medicine:

STAMARIL, powder and solvent for suspension for injection in pre-filled syringe.

Yellow fever vaccine (Live).

THE DIRECTOR GENERAL OF THE NATIONAL AGENCY FOR MEDICINES AND HEALTH PRODUCTS SAFETY

Considering the Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products, as well as the guidelines pertaining to its implementation;

Considering the Public Health Code Volume V, especially articles L.5121-8, L.5121-20, R. 5121-21 and following;

Considering the marketing authorisation granted on 27 January 1986; modified

Considering the application for modification to the marketing authorisation submitted by:
SANOFI PASTEUR
on 20 January 2020;

Considering the commitment to compliant translation of the annexes to the Marketing Authorisation submitted by:
SANOFI PASTEUR
on 24 December 2020;

and concerning:

- the following sections of the Summary of Product Characteristics:

  4.1. Therapeutic indications
  4.2. Posology and method of administration
  4.3. Contraindications
  4.4. Special warnings and precautions for use
  4.5. Interaction with other medicinal products and other forms of interaction
  4.6. Fertility, pregnancy and lactation
  4.8. Undesirable effects

  As well as the corresponding sections of the Patient Leaflet.

Decides

Article 1

The marketing authorisation for the proprietary medicine **STAMARIL, powder and solvent for suspension for injection in pre-filled syringe. Yellow fever vaccine (Live)** held by **SANOFI PASTEUR** is modified.

Article 2

The information enclosed with the present decision replaces the corresponding information in the annexes of the marketing authorisation in effect.

Article 3

The present decision has been notified to the interested party.

11 January 2021

Division of Data Flows and Repositories
Interim Head of Instruction and Notification of Dossiers Unit
Florence MONTANIER

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

STAMARIL, powder and solvent for suspension for injection in pre-filled 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.

Excipient with known effect:

This product contains about 8 mg of sorbitol (E420) per dose.

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 homogeneous, beige to orange beige, and the solvent is a clear and colourless solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

- travelling to, passing through or living in an area where there is a persisting or periodical risk of yellow fever transmission
- 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.

See the regular updates related to obligations and recommendations for yellow fever vaccination on the dedicated site of the World Health Organisation (WHO) or on the official sites of local health authorities.

In order to comply with vaccine regulations and to be officially recognised, yellow fever vaccines must be administered by a qualified and trained health professional in an approved WHO vaccination centre and registered on an International Certificate of Vaccination. The validity period of this Certificate is established according to International Health Regulations (IHR) recommendations, and starts 10 days after primary vaccination and immediately after re-vaccination (see section 4.2).

4.2 Posology and method of administration

Posology

Primary vaccination

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.

Adults: a single dose of 0.5 mL of the reconstituted vaccine.

Persons aged 60 years and older:

The dose is the same as for adults. However due to a potentially 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 significant and unavoidable risk of acquiring yellow fever infection, such as in case of travel in an area where there is persisting or periodical risk of yellow fever transmission (see sections 4.4 and 4.8).

Paediatric population:

- *Children aged 9 months and older*: a single dose of 0.5 mL of the reconstituted vaccine.
- *Children from 6 to 9 months of age*: vaccination against yellow fever is not 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 children aged 9 months and older.
- *Children under 6 months of age:* STAMARIL is contraindicated in children less than 6 months of age (see section 4.3).

Re-vaccination

The duration of protection following administration of one single 0.5 mL dose of STAMARIL is expected to be at least 10 years and may be life-long.

According to the recommendations of WHO and International Health Regulations, a yellow fever vaccination certificate is valid for the entire life of the vaccinated person. However, re-vaccination with one dose of 0.5 mL may be needed in subjects who had an insufficient immune response after their primary vaccination and are still at risk of infection with the yellow fever virus. Re-vaccination may also be required according to official recommendations of local Health Authorities.

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 children less than 12 months of age, the anterolateral aspect of the thigh (or the deltoid muscle if muscle mass is adequate) in children 12 months through 35 months of age or the deltoid muscle in children from 36 months of age onwards and adults.

DO NOT INJECT INTRAVASCULARLY.

Precautions to be taken before handling or administering the medicinal product

For instructions on reconstitution of the medicinal product before administration, see section 6.6.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1 or to eggs or chicken proteins.
- Severe hypersensitivity reactions (*e.g.*, anaphylaxis) after a previous dose of any yellow fever vaccine.
- Age less than 6 months (see sections 4.2 and 4.4).
- Immunosuppression, whether congenital or acquired. This includes individuals receiving immunosuppressive therapies, such as treatment with high-dose systemic steroids (for example, a daily dose of 20 mg or 2 mg/kg body weight of prednisone or the equivalent for 2 weeks or more or a daily dose of 40 mg or more of prednisone for more than one week), any other medicinal product including biological products with known immunosuppressive properties, radiotherapy, cytotoxic drugs or any other situation that may cause immunodepression.
- History of thymus dysfunction (including *myasthenia gravis,* thymoma).
- Thymectomy (regardless of cause).
- Symptomatic HIV infection.
- Asymptomatic HIV infection when accompanied by evidence of impaired immune function (see section 4.4).
- Moderate or severe febrile illness or acute illness.

4.4 Special warnings and precautions for use

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly registered.

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.

Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. Procedures should be in place to prevent injury from faints and manage syncopal reactions.

DO NOT INJECT INTRAVASCULARLY.

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.

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, YEL-AND has been reported following vaccination, with sequelae or with fatal outcome in some cases (see section 4.8). To date, most of cases of YEL-AND have been reported in primary vaccinees with an onset within 30 days of vaccination. The risk appears to be higher in those aged over 60 years and below 9 months of age (including infants exposed to vaccine through breast-feeding), although cases have been also reported in other age groups. Congenital or acquired immunodeficiency has also been recognised as a predisposing factor (see section 4.3). However, YEL-AND cases have also been reported in persons without identified risk factors. The vaccinated persons must be informed of the need to request a medical opinion if they feel, after vaccination, any symptoms indicative of YEL-AND such as high fever together with headache or confusion, personality change, or if they feel extreme fatigue, neck stiffness, seizures, loss of movement or feeling in part or all of the body. Vaccinated persons should also be reminded to inform their health care provider that they received a yellow fever vaccine (see section 4.8).

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

Very rarely, YEL-AVD resembling fulminant infection by wild-type virus has been reported following vaccination (see section 4.8). The mortality rate has been around 60%. To date, most of cases of YEL-AVD have been reported in primary vaccinees with an 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 other age groups. Thymectomy or history of thymus dysfunction has also been recognised as predisposing factors (see section 4.3). However, YEL-AVD cases have also been reported in persons without identified risk factors.

The vaccinated persons must be informed of the need to request a medical opinion if they feel, after vaccination, any symptoms indicative of YEL-AVD such as fever, myalgia, fatigue, headache or hypotension, because these symptoms can potentially rapidly progress to liver dysfunction with jaundice, muscle cytolysis, thrombocytopenia and acute respiratory and renal failure. Vaccinated persons should also be reminded to inform their health care provider that they received a yellow fever vaccine (see 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

Paediatric population: children less than 9 months of age

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.

STAMARIL is contraindicated in children less than 6 months of age (see section 4.3).

Older people: persons aged 60 years and older

Persons aged 60 years and older may have an increased risk of serious and potentially fatal adverse reactions (including systemic and neurological reactions persisting more than 48 hours, YEL-AVD and YEL-AND) when compared to other age groups. Therefore, the vaccine should only be given to those who visit areas where there is a risk of yellow fever transmission at the time of travel. The countries designated by WHO, where vaccination is not recommended generally, or not recommended, should be considered as not presenting an inevitable significant risk (refer to the list of countries with yellow fever infection risk updated by WHO) (see above and section 4.8).

Pregnant and breast-feeding women

STAMARIL should not be used in pregnant and breast-feeding woman unless when clearly needed and following an assessment of the risks and benefits (see section 4.6).

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 YEL-AND from which the infants recover (see section 4.6).

As with any vaccine, vaccination with STAMARIL may not protect 100% of vaccinated individuals.

Latex

The tip-caps of the prefilled syringes contain a natural latex derivative that could cause allergic reactions in people sensitive to latex.

Excipients with a known effect

STAMARIL contains less than 1 mmol (23 mg) of sodium per dose, i.e. it is essentially "sodium-free."

STAMARIL contains less than 1 mmol (39 mg) of potassium per dose, i.e. it is essentially "potassium-free".

STAMARIL contains about 8 mg of sorbitol (E420) per dose.

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).

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

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

It must not be administered to persons who are receiving immunosuppressant therapies such as treatment with high-dose systemic steroids (for example, a daily dose of 20 mg or 2 mg/kg body weight of prednisone or the equivalent for 2 weeks or more or a daily dose of 40 mg or more of prednisone for more than one week), any other medicinal product including biological products with known immunosuppressive properties, radiotherapy, cytotoxic drugs or any other situation that may cause

immunodepression, (see section 4.3). In case of uncertainty regarding the degree of immunosuppression, vaccination should be suspended and the opinion of a specialist should be requested.

It can induce false positive results with laboratory and/or diagnostic tests for other flavivirus related diseases such as dengue or Japanese encephalitis.

4.6 Fertility, pregnancy and lactation

Pregnancy

No animal developmental and reproductive 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 foetus/new-born child. Nevertheless, as STAMARIL is a live attenuated vaccine, it should not be used during pregnancy unless clearly needed and only after careful consideration of the potential risks and benefits. Pregnancy should be avoided in the month after the vaccination.

Breast-feeding

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 and only if the potential benefits to the mother are higher than the potential risks, including those for the breastfed child (see section 4.4). In the case where vaccination is needed, it is recommended to discontinue breast-feeding for at least 2 weeks after vaccination.

Fertility

No animal fertility studies have been conducted with STAMARIL and no fertility data are available in humans.

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

a. Summary of the safety profile

Cases of serious adverse events such as severe hypersensitivity or anaphylactic reactions, neurotropic or viscerotropic disease (YEL-AND; YEL-AVD) have been reported from post-marketing experience (see subsections **b. Tabulated list of adverse reactions** and **c. Description of selected adverse reactions**).

In all clinical studies, 4896 subjects (all ages) received STAMARIL.

In the most representative study in general population, the most frequently reported reactions (between 12% and 18% of subjects) were cephalalgia, asthenia, injection site pain and myalgia.

In the most representative study in toddler population, the most frequently reported reactions (between 32% and 35% of toddlers) were irritability, crying and appetite loss.

Adverse reactions usually occurred within the first three days following vaccination except fever, which occurred between Day 4 and Day 14.

These reactions usually lasted for not more than 3 days.

Both local and systemic reactions were usually of mild intensity; however at least one severe injection site reaction was reported in 0.8% of subjects in general population and in 0.3% of toddlers and at least one severe systemic reaction was reported in 1.4% of subjects in general population and 4.9% in toddlers.

b. Tabulated list of adverse reactions

The table below summarises the frequencies of the adverse reactions that were recorded following vaccination with STAMARIL during clinical studies and worldwide post-marketing experience.

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

Very common (≥ 1/10)

Common (≥ 1/100 to < 1/10)
Uncommon (≥ 1/1,000 to < 1/100)
Rare (≥ 1/10,000 to < 1/1,000)
Very rare (< 1/10,000)
Not known (cannot be estimated from available data)

Adverse reactions in each frequency group are presented in the decreasing order of severity.

System Organ Class	Frequency	Adverse reactions
Infections and infestations	Rare	Rhinitis
	Very rare	YEL-AVD‡
Blood and Lymphatic System Disorders	Not known	Lymphadenopathy
Immune System Disorders	Not known	Anaphylactoid reaction including angioedema
Metabolism and nutrition disorders	Very common	Appetite loss*
Nervous System Disorders	Very common	Drowsiness*, Cephalalgia
	Uncommon	Dizziness
	Very rare	YEL-AND‡, seizures, aseptic meningitis
	Not known	Paraesthesia
Gastrointestinal disorders	Very common	Vomiting†
	Common	Nausea
	Uncommon	Abdominal pain
	Rare	Diarrhoea
Skin and Subcutaneous tissue Disorders	Common	Rash
	Uncommon	Pruritus
	Not known	Urticaria
Musculoskeletal and Connective Tissue Disorders	Very common	Myalgia
	Common	Arthralgia
General Disorders and Administration Site Conditions	Very common	Irritability*, Crying*, Fever†, Asthenia, Injection site pain/tenderness
	Common	Injection site erythema/redness, Injection site haematoma, Injection site induration; Injection site oedema/swelling
	Uncommon	Injection site papule
	Not known	Influenza-like illness

*Specific to paediatric population, (see section **d. Paediatric population**)

‡ For clinical features see section **c. Description of selected adverse reactions**

† Very common in toddlers (see section **d. Paediatric population**), Common in general population

c. Description of selected adverse reactions

Cases of neurotropic disease (known as YEL-AND), some of which have had a fatal outcome, have been reported to occur within 30 days following vaccination with STAMARIL, and other yellow fever vaccines. YEL-AND may manifest either as an encephalitis (with or without demyelination), or as a neurobiological disease affecting the peripheral nervous system (for example Guillain-Barré syndrome). Encephalitis usually starts with high fever with cephalalgia that may progress to encephalopathy (for example confusion, lethargy, personality change for more than 24h, focal neurological deficits, cerebellar dysfunction or seizures. YEL-AND affecting the peripheral nervous system manifests

generally with bilateral weakness of the limbs, or peripheral paresis of the cranial nerves with reduction or disappearance of tendon reflexes (see section 4.4).

Neurological diseases not fulfilling the YEL-AND criteria have been reported. The manifestations may include cases of aseptic meningitis or seizures not associated with focal neurological signs. These cases are generally of mild or moderate severity and resolve spontaneously.

Cases of viscerotropic disease (known as YEL-AVD and formerly described as “Febrile Multiple Organ-System Failure”) have been reported following vaccination with STAMARIL, and other yellow fever vaccines, some of which have been fatal. In the majority of cases reported, the onset of signs and symptoms was within 10 days after the vaccination. Initial signs and symptoms are non-specific and may include fever, myalgia, fatigue, cephalalgia and hypotension, potentially progressing quickly to liver dysfunction with jaundice, muscle cytolysis, thrombocytopenia and acute respiratory and renal failure (see section 4.4).

d. Paediatric population

The safety of STAMARIL in paediatric population has been studied through a clinical study performed in 393 toddlers aged 12 to 13 months who received STAMARIL and placebo concomitantly.

The safety profile was assessed during the first 4 weeks following vaccination.

The following most frequently reported adverse reactions specific to the paediatric population were reported as “very common”: irritability (34.7%), appetite loss (33.7%), crying (32.1%) and drowsiness (22%).

The other adverse reactions reported in toddlers were also reported from studies in general population:

- Injection site pain (17.6%), fever (16.5%) and vomiting (17.1%) were reported as “very common” in toddlers. Fever and vomiting were more frequently reported than in general population (see table in subsection **b. Tabulated summary of adverse reactions**).
- Injection site erythema (9.8%) and injection site swelling (4.4%) were reported as “common” in toddlers, like in general population, however with significantly higher frequencies compared to general population.

e. Other special population

Congenital or acquired immunodeficiency has been recognised as a potential risk factor for serious adverse events, including YEL-AND (see sections 4.3 and 4.4).

Age of more than 60 years (see section 4.4) has been recognised as a potential risk factor for YEL-AVD and YEL-AND.

Age below 9 months (including infants exposed to vaccine through breast-feeding) (see section 4.4) has been recognised as a potential risk factor for YEL-AND.

A medical history of thymus dysfunction or thymectomy (see sections 4.3 and 4.4) have been recognised as predisposing factors for YEL-AVD.

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” - Website: www.signalement-sante.gouv.fr.

4.9 Overdose

Cases of administration of more than the recommended dose (overdose) have been reported with STAMARIL. When adverse reactions were reported, the information was consistent with the known safety profile of STAMARIL described in section 4.8.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Yellow Fever Vaccine (Live), ATC code: J07B-L01.

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. A neutralising antibody titre of 1:10 is assumed to correlate with protection.

Protective immunity appears from about 10 days after vaccination, lasts at least 10 years and may be life-long.

In clinical studies in adults it has been shown that 28 days following vaccination with STAMARIL seroconversion rates of 93% and 100% were obtained.

Paediatric population

In a clinical study conducted in 337 toddlers aged 12 to 13 months the yellow fever seropositivity rates 28 days post injection of STAMARIL were 99.7% (98.5; 100.0) and the Geometric Mean Titres were 423 (375; 478). In another clinical study conducted in 30 children and adolescents aged 2 to 17 years a seroconversion rate of 90 to 100% was observed, confirming results observed in earlier clinical studies.

5.2 Pharmacokinetic properties

No pharmacokinetic studies have been performed.

5.3 Preclinical safety data

No non-clinical studies have been performed.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Powder:

Lactose
Sorbitol E420
L-Histidine hydrochloride
L-Alanine
Sodium chloride
Potassium chloride
Disodium phosphate dihydrate
Potassium dihydrogen 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 of powder and the syringe of solvent in the outer carton in order to protect from light.

For storage conditions after reconstitution of the 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 pre-filled syringe (type I glass), with a plunger-stopper (halobutyl), and 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 pre-filled syringe (type I glass), with a plunger-stopper (halobutyl), and a tip cap (styrene butadiene) – box of 1 or 10. The tip-caps of the pre-filled syringes contain a natural latex derivative.

Powder in vial (type I glass), with a stopper (chlorobutyl) and a flip-off cap (aluminium) + 0.5 mL of solvent in pre-filled syringe (type I glass), with a plunger-stopper (halobutyl), and a tip cap (styrene butadiene) with 1 or 2 separate needle(s) provided in the blister – box of 1 or 10. The tip-caps of the pre-filled syringes contain a natural latex derivative.

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, 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 of powder. The vial is shaken and, after complete dissolution, the suspension obtained is withdrawn into the same syringe for injection.

Before administration, the reconstituted vaccine should be vigorously shaken.

Use immediately after reconstitution.

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

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

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

SANOFI PASTEUR
14 ESPACE HENRY VALLÉE
69007 LYON

8. MARKETING AUTHORISATION NUMBER(S)

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

- 34009 300 576 6 7: powder in vial (type I glass), with a stopper (chlorobutyl) + 0.5 mL of solvent in pre-filled syringe (type I glass), with a plunger-stopper (halobutyl), and a tip-cap (styrene butadiene), with 1 separate needle – box of 1.
- 34009 300 576 9 8: powder in vial (type I glass), with a stopper (chlorobutyl) + 0.5 mL of solvent in pre-filled syringe (type I glass), with a plunger-stopper (halobutyl), and a tip-cap (styrene butadiene), with 1 separate needle - box of 10.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[to be completed at a later date by the holder]

10. DATE OF REVISION OF THE TEXT

[to be completed at a later date by the holder]

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 MANUFACTURER(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
27100 VAL DE REUIL
FRANCE

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

The name and address of the manufacturer responsible for batch release should appear on the package leaflet of the medicinal product.

SANOFI PASTEUR
1541 AVENUE MARCEL MERIEUX
69280 MARCY L'ETOILE
FRANCE

or

SANOFI PASTEUR
PARC INDUSTRIEL D'INCARVILLE
27100 VAL DE REUIL
FRANCE

or

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

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Reserved for vaccination centres authorised to perform yellow fever vaccination.

- Official batch release

In accordance with Article 114 of Directive 2001/83/EC, the official batch release will be undertaken by a state laboratory or a laboratory designated for that purpose.

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

- **Periodic Safety Update Reports (PSUR)**

The requirements for submission of periodic safety update reports for this medicinal product are set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and any subsequent updates published on the European medicines web-portal.

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

Not applicable.

E. SPECIFIC OBLIGATION TO COMPLETE POST-AUTHORISATION MEASURES FOR THE MARKETING AUTHORISATION UNDER EXCEPTIONAL CIRCUMSTANCES

Not applicable.

F. QUALITATIVE AND QUANTITATIVE COMPOSITION IN EXCIPIENTS

One dose (0.5 mL) of STAMARIL 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 dihydrate	0.298 mg
Potassium dihydrogen phosphate	0.063 mg
Calcium chloride	0.039 mg
Magnesium sulphate	0.029 mg

One dose (0.5 mL) of solvent for reconstitution of STAMARIL 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

STAMARIL - Carton for vial 0.5 mL and pre-filled syringe with attached needle, with 1 or 2 separate needles or without needle – Box of 1, 10 or 20.

1. NAME OF THE MEDICINAL PRODUCT

STAMARIL

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

Yellow fever vaccine (Live).

2. STATEMENT OF ACTIVE SUBSTANCES

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.

3. LIST OF EXCIPIENTS

Powder: lactose, sorbitol, L-Histidine hydrochloride, L-Alanine, sodium chloride, potassium chloride, disodium phosphate dihydrate, potassium dihydrogen 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 pre-filled syringe.

<(Powder in vial + 0.5 mL of solvent in pre-filled syringe with attached needle). Box of 1.>

<(Powder in vial + 0.5 mL of solvent in pre-filled syringe with attached needle). Box of 10.>

<(Powder in vial + 0.5 mL of solvent in pre-filled syringe with attached needle). Box of 20.>

<(Powder in vial + 0.5 mL of solvent in pre-filled syringe with 1 separate needle). Box of 1.>

<(Powder in vial + 0.5 mL of solvent in pre-filled syringe with 1 separate needle). Box of 10.>

<(Powder in vial + 0.5 mL of solvent in pre-filled syringe with 2 separate needles). Box of 1.>

<(Powder in vial + 0.5 mL of solvent in pre-filled syringe with 2 separate needles). Box of 10.>

<(Powder in vial + 0.5 mL of solvent in pre-filled syringe without needle). Box of 1.>

<(Powder in vial + 0.5 mL of solvent in pre-filled syringe without needle). Box of 10.>

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 SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Not applicable.

8. EXPIRY DATE

EXP {MM/YYYY}

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator. Do not freeze. Keep the vial of powder and the syringe of solvent 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
14 ESPACE HENRY VALLÉE
69007 LYON
FRANCE

Distributor

SANOFI PASTEUR EUROPE
14 ESPACE HENRY VALLÉE
69007 LYON
FRANCE

12. MARKETING AUTHORISATION NUMBER(S)

Authorised medicinal product No:

13. BATCH NUMBER

Batch {number}

14. GENERAL CLASSIFICATION FOR SUPPLY

Reserved for vaccination centres authorised to perform yellow fever vaccination.

15. INSTRUCTIONS ON USE

This vaccine is indicated for active immunisation against yellow fever.

16. INFORMATION IN BRAILLE

[Comply with the decision of May 7, 2008 taken pursuant to article R. 5121-138 of the Public Health Code, published in the OJ of May 22, 2008]

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC: {number}

SN: {number}

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

Pictogram on teratogenic or foetotoxic effects

Where applicable, the pictogram mentioned in section III of article R. 5121-139 of the Public Health Code (teratogenic or foetotoxic effects) must be affixed in compliance with the implementing decree provided for in the same article.

Pictogram on effects on the ability to drive

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

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

STAMARIL - Vial of powder, single dose / Pre-filled syringe of solvent, 4 mg/mL (0.4%) sodium chloride solution

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

<STAMARIL

Powder

Yellow fever vaccine (Live)

SC or IM after reconstitution>

<Solvent for STAMARIL reconstitution>

2. METHOD OF ADMINISTRATION

Not applicable.

3. EXPIRY DATE

EXP {MM/YYYY}

4. BATCH NUMBER

Batch {number}

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

<1 dose>

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

6. OTHER

Sanofi Pasteur Europe

ANNEX IIIB

PACKAGE LEAFLET: INFORMATION FOR THE USER

Name of the medicinal product

STAMARIL, powder and solvent for suspension for injection in pre-filled syringe.

Yellow fever vaccine (Live).

Boxed text

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, powder and solvent for suspension for injection in pre-filled syringe IS AND WHAT IT IS USED FOR

Pharmacotherapeutic group: Yellow Fever Vaccine (Live), ATC code: J07B-L01.

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, powder and solvent for suspension for injection in pre-filled syringe

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, powder and solvent for suspension for injection in pre-filled syringe 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, powder and solvent for suspension for injection in pre-filled syringe

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.

STAMARIL, powder and solvent for suspension for injection in pre-filled syringe with food and drink

Not applicable.

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.

Driving and using machines

Not applicable.

STAMARIL, powder and solvent for suspension for injection in pre-filled syringe, 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, powder and solvent for suspension for injection in pre-filled syringe

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, powder and solvent for suspension for injection in pre-filled syringe 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, powder and solvent for suspension for injection in pre-filled syringe 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 or your child forget to use STAMARIL, powder and solvent for suspension for injection in pre-filled syringe

Not applicable.

If you or your child stop using STAMARIL, powder and solvent for suspension for injection in pre-filled syringe

Not applicable.

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. 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" - Website: www.signalement-sante.gouv.fr.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE STAMARIL, powder and solvent for suspension for injection in pre-filled syringe

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, powder and solvent for suspension for injection in pre-filled syringe 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

Marketing authorisation distributor

SANOFI PASTEUR EUROPE
14 ESPACE HENRY VALLÉE
69007 LYON
FRANCE

Manufacturer

SANOFI PASTEUR
14 ESPACE HENRY VALLÉE

69007 LYON
FRANCE

or

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

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

This medicinal product is authorised in the Member States of the EEA under the following name: In accordance with official recommendations.

[To be completed later by the holder]

This leaflet was last revised in:

{MM/YYYY}

Other

Detailed information on this medicine is available on the website of ANSM (France).

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, powder and solvent for suspension for injection in pre-filled syringe.**