Prescribing Information: STAMARIL® Powder and solvent for suspension for injection in a pre-filled syringe (Yellow fever vaccine (Live))

Please refer to Summary of Product Characteristics (SmPC) before prescribing.

Presentation: Available as a powder and solvent for suspension for injection in pre-filled syringe. One dose (0.5 mL) of the reconstituted vaccine contains the live, attenuated 17D-204 strain of the yellow fever virus, not less than 1000 IU.

Indication: Active immunisation against yellow fever in adults and children aged ≥9 months, for persons travelling to, passing through or living in an area where there is a current or periodic 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). For updated yellow fever vaccination requirements and recommendations consult the WHO dedicated website or refer to resources provided by national health authorities.

Dosage and Administration: STAMARIL is to be used on the basis of official recommendations. Adults and children aged 9 months and over: A single dose of 0.5 mL of reconstituted vaccineThe 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. 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. In accordance with WHO advice and International Health Regulations, the validity of a certificate of vaccination against yellow fever shall extend for the life of the person vaccinated. However, re-vaccination with one dose of 0.5 mL may be needed in individuals who had an insufficient immune response after their primary vaccination if they continue to be at risk for yellow fever virus infection. Re-vaccination may also be required, depending on official recommendations of local Health Authorities. It is preferable to give the reconstituted vaccine by subcutaneous (SC) injection. Intramuscular (IM) injection may be performed if this is in accordance with applicable official recommendations. For IM 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.

Special Populations: Paediatric population: 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, in which case the dose is the same as in children aged 9 months and older. The vaccine must not be given to children less than 6 months old. Elderly: 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 (including systemic and neurological reactions persisting more than 48 hours, YEL-AVD and YEL-AND) in persons aged 60 years and older, 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 travel to an area where there is current or periodic risk of yellow fever transmission. Countries designated by WHO as where vaccination is not generally recommended, or not recommended, should be considered as not representing a significant and unavoidable risk.

Contraindications: Hypersensitivity reactions to eggs, chicken proteins or any component of STAMARIL®; severe hypersensitivity reaction to any yellow fever vaccine; immunosuppression (congenital or acquired, includes individuals receiving immunosuppressive therapies such as treatment with high-dose systemic corticosteroids, any other medicinal products including biologicals with known immunosuppressive properties, radiotherapy, cytotoxic drugs or any other condition which may result in immunocompromised status); history of thymus dysfunction (including *myasthenia gravis*, thymoma); thymectomy (for any reason); symptomatic HIV infection; asymptomatic HIV infection when accompanied by evidence of impaired immune function; moderate or severe febrile illness or acute illness. Age less than 6 months.

Warnings and Precautions: As with any vaccine, vaccination with STAMARIL may not protect 100% of vaccinated individuals. Prior to immunisation: Appropriate treatment and supervision should be readily available in case of anaphylaxis or other severe hypersensitivity reaction following vaccine administration. STAMARIL should only be administered to persons who are/ will be at risk of infection or in cases 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. *Yellow-fever vaccine associated neurotropic disease (YEL-AND) and Yellow fever vaccine-associated viscerotropic disease (YEL-AVD):* There are some reported cases of YEL-AND and YEL-AVD with a fatal outcome. Cases of YEL-AND have been reported to occur within 30 days following vaccination and may manifest as either encephalitis (with or without demyelination), or as a neurologic disease with peripheral nervous system involvement (e.g. Guillain-Barré syndrome). Encephalitis usually starts with high fever with headache that may progress to include encephalopathy (e.g. confusion, lethargy, personality change lasting more than 24 hours), focal neurologic deficits, cerebellar dysfunction or seizures. YEL-AND with peripheral nervous system involvement usually manifests as bilateral limb weakness or peripheral cranial nerve paresis with decreased or absent tendon reflexes. YEL-AVD have been reported with onset of signs and symptoms within 10 days after vaccination in majority of cases reported. They may include pyrexia, fatigue, myalgia, headache and hypotension progressing to liver dysfunction with jaundice, muscle cytolysis, thrombocytopenia, and acute respiratory and renal failure. For YEL-AND, the risk appears higher in those aged over 60 years and below 9 months of age. Congenital or acquired immunodeficiency has also been recognised as a predisposing condition. For YEL-AVD, risk appears higher in those aged over 60 years. Medical history of thymus dysfunction or thymectomy are predisposing conditions for YEL-AVD. Vaccinees should be instructed to seek medical attention if they experience any symptoms suggestive of YEL-AND or YEL-AVD, and should also be reminded to inform their healthcare professional that they received yellow fever vaccine. See

SmPC for further details. *Immunosuppressed persons:* STAMARIL must not be administered to immunosuppressed persons. 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 administrated to persons with symptomatic HIV infection or with asymptomatic HIV infection when accompanied by evidence of impaired immune function. Official guidance should be taken into account when considering the risks and benefits of vaccinating an asymptomatic HIV-infected person who cannot avoid travel to an endemic area. Children aged at least 6 months born to HIV positive mothers 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. Administration precautions: 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. IM injection can cause injection site haematoma; STAMARIL should not be given by the IM route to persons with any bleeding disorder, such as haemophilia or thrombocytopenia, or to persons on anticoagulant therapy. The SC route of administration should be used instead. The tip caps of the pre-filled syringes contain a natural rubber latex derivative, which may cause allergic reactions in latex sensitive individuals. Excipients of known effect: STAMARIL contains less than 1 mmol sodium (23 mg) and less than 1 mmol of potassium (39 mg) per dose that is to say essentially “sodium free” and “potassium free”. STAMARIL contains approximately 8 mg of sorbitol (E420) per dose.

Interactions: 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 immunosuppressive therapies, high-dose systemic corticosteroids (e.g. daily dose of 20 mg or 2 mg/kg body weight of prednisone or equivalent for 2 weeks or more or daily dose of 40 mg or more of prednisone for more than one week), any other medicinal products including biologicals with known immunosuppressive properties, radiotherapy, cytotoxic drugs or any other condition which may result in immunocompromised status. It can induce false positive results with laboratory and/or diagnostic tests for other flavivirus related diseases such as dengue or Japanese encephalitis.

Fertility, pregnancy and lactation: *Data on a limited number of exposure pregnancies indicate no adverse effects of STAMARIL on pregnancy or the health of the fetus/newborn. Nevertheless,* as STAMARIL is a live attenuated vaccine, it should not be given during pregnancy unless when clearly needed and only after careful consideration of the potential risks and benefits. Pregnancy should be avoided for one month following vaccination. 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 outweigh the potential risks, including those to the breastfed child (infants may develop YEL-AND following transmission, from which they recover). In case vaccination is needed, it is recommended to interrupt breast-feeding for at least 2 weeks following vaccination.

Adverse Reactions: Very common: headache, myalgia, asthenia and injection site pain/tenderness. *Paediatric population*: Appetite loss, drowsiness, irritability, crying, yrexia and vomiting. Common: arthralgia, nausea, rash, injection site reactions (erythema/redness, haematoma, induration, oedema/swelling) Other Serious Adverse Drug Reactions: *Rare/Very rare:* YEL-AVD, YEL-AND, seizure, meningitis asceptic, diarrhoea. *Frequency not known*: Anaphylactoid reaction including angioedema and severe hypersensitivity, paraesthesia, urticaria, influenza-like illness. *Prescribers should consult the SmPC in relation to other adverse reactions.*

List price: Single pack containing vial of lyophilised powder with 0.5 mL diluent in a syringe with 2 separate needles: £39.72

Legal Category: POM.

Marketing Authorisation Number: PL 23228/0005

Marketing Authorisation Holder: Sanofi Winthrop Industrie, 82 avenue Raspail, 94250 Gentilly, France.

Further information is available from: Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK. uk-medicalinformation@sanofi.com

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Adverse events should also be reported to the Sanofi drug safety department on Tel: 0800 0902 314. Alternatively, send via email to UK-drugsafety@sanofi.com