**For the use only of a Registered Medical Practitioners or a Hospital or a Laboratory**

Abridged Prescribing Information
Yellow Fever Vaccine (Live) I.P.
**STAMARIL**®

## QUALITATIVE & 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:

Single dose presentation
This product contains about 8mg of sorbitol (E420) per dose.
Multidose presentation
This product contains about 1mg of sorbitol (E420) per dose.

## 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).

## 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 this a persisting or periodical risk of yellow fever transmission.
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.

**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 of prescribing information.

**CONTRAINDICATIONS:** A history of severe allergic reactions to the active substance or to any of the excipients listed above or to eggs or chicken proteins; A history of severe allergic reactions after previous administration of the vaccine or a vaccine containing the same components; Age less than 6 months; Congenital or acquired immune deficiency that impairs cellular immunity; History of thymus dysfunction (including myasthenia gravis, thymoma or thymectomy);Symptomatic HIV infection; Asymptomatic HIV infection when accompanied by evidence of impaired immune function; Postpone vaccination in case of moderate or severe febrile illness or acute illness.

**SPECIAL WARNINGS AND PRECAUTIONS FOR USE:**

• Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. 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. 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.

• Yellow fever vaccine-associated neurotropic disease (YEL-AND) Yellow fever vaccine-associated viscerotropic disease (YEL-AVD)

• Immunosuppressed persons: STAMARIL must not be administered to immunosuppressed persons.

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.

• Children born to HIV positive mothers

• 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.

Older people: persons aged 60 years and older

• 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.

• 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.

**DRUG 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 measles vaccine, 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 immunosuppression, vaccination should be suspended, and the opinion of a specialist should be requested.

**PREGNANCY AND LACTATION:** STAMARIL should not be used in pregnant and breast-feeding woman unless when clearly needed and following an assessment of the risks and benefits

**UNDESIRABLE EFFECTS:**
**Common:** Nausea, ,Rash, Arthralgia.
**Very Common:** Appetite loss*, Drowsiness*, Cephalalgia, Vomiting, Myalgia, Irritability*, Crying, Fever†, Asthenia, Injection site pain/tenderness.
**Uncommon:** Dizziness, Abdominal pain, Pruritus, Injection site papule.
**Rare:** Rhinitis, Diarrhoea.
**Very Rare:** YEL-AVD
**Not known:** Transient moderate leucopenia, Lymphadenopathy, Anaphylactoid reaction including angioedema; Paraesthesia, Syncope; Urticaria, Influenza-like illness.
*Specific to paediatric population, ‡ For clinical features † Very common in toddlers, Common in general population.

**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

**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

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