Abridged Prescribing information
For the use of a Registered Medical Practitioner or a hospital or a laboratory

YELLOW FEVER VACCINE (LIVE) I.P.

STAMARIL®

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.

List of excipients:-
Lactose, Sorbitol E420, L-Histidine hydrochloride, L-Alanine, Sodium chloride, Potassium chloride, Disodium phosphate dehydrate, Potassium dihydrogen phosphate, Calcium chloride, Magnesium sulphate, Sodium chloride, Water for injections.

THERAPEUTIC INDICATIONS

STAMARIL is indicated for active immunisation 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 dosage and administration 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. 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.

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. This includes subjects receiving immunosuppressive therapies, such as chemotherapy, or high doses of systemic corticosteroids. (A substantially immunosuppressive dose of corticosteroids is considered to be daily intake of 20 mg or 2 mg/kg body weight of prednisone or equivalent for 2 weeks or more)
- 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.

WARNINGS AND PRECAUTIONS

- 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
- 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

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

Very rarely, YEL-AVD resembling fulminant infection by wild-type virus has been reported following vaccination

- 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 administered to persons with symptomatic HIV infection or with asymptomatic HIV infection when accompanied by evidence of impaired immune function. 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 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.

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 have a significant risk of acquiring yellow fever.

- 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.

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

DOSAGE AND 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.
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, 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

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.
• Re-vaccination with one dose of 0.5 ml may be needed in some individuals who had an insufficient immune response after their primary vaccination.
• Re-vaccination may also be required, depending on official recommendations of local health authorities, as a condition of entry in some countries.

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

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).

It may be administered at the same time as measles vaccine, vaccines containing typhoid Vi capsular polysaccharide and/or inactivated hepatitis A virus. It may also be administered in adults at the same time as live attenuated Japanese encephalitis recombinant vaccine

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

SAFETY RELATED INFORMATION

The table below summarizes 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)

System Organ Class	Frequency	Adverse reactions
Infections and infestations	Rare	Rhinitis
	Very rare	YEL-AVD‡
Blood and Lymphatic System Disorders	Not known	Transient moderate leucopenia, 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‡
	Not known	Paraesthesia, Syncope
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	Very common	Myalgia

Connective Tissue Disorders	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,
‡ For clinical features
† Very common in toddlers, Common in general population

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