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®

COMPOSITION

After reconstitution, 1 dose (0.5 ml) contains:

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

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).

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.

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; Do not inject intravascularly;

Precautions to be taken before handling or administering the medicinal product.

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

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.

WARNINGS AND PRECAUTIONS

- 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.

ADVERSE REACTIONS

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.

For full prescribing information, please contact Sanofi Healthcare India Pvt. Ltd., Sanofi House, CTS No. 117B, L&T Business Park, Saki Vihar Road, Powai, Mumbai 400 072, India

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