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DOCUMENT 2.

PRODUCT INFORMATION
STAMARIL®
[Yellow Fever Vaccine (Live), Stabilised]

NAME OF PREPARATION

Yellow Fever Vaccine (Live), Stabilised.

DESCRIPTION

Each 0.5 mL dose of reconstituted vaccine from the freeze-dried product contains an injectable suspension in stabiliser of the attenuated 17D strain of yellow fever virus. The virus has been propagated in specific pathogen-free chick embryos, in particular free from avian leucosis viruses. Each dose contains not less than 1000 mouse LD_{50} units.

Other ingredients:-

Stabilising medium:	16.0 mg lactose, 8.0 mg sorbitol, 833 µg L-histidine hydrochloride, 362 µg L-alanine, 1.6 mg sodium chloride, 54 µg potassium chloride, 598 µg sodium phosphate - dibasic dodecahydrate, 63 µg potassium phosphate-monobasic, 39 µg calcium chloride, 29 µg magnesium sulfate.
Diluent:	0.4% sodium chloride solution.

Stamaril® has been manufactured in a facility approved by the World Health Organization.

PHARMACOLOGY

Stamaril® is a live stabilised vaccine for active immunisation against yellow fever. Immunity appears 7 to 10 days after injection and lasts at least 10 years.

INDICATIONS

Prevention of yellow fever. Vaccination is recommended for:

- Every person over 6 months of age living in or travelling through an endemic area.
- Non vaccinated persons moving from an endemic to a non-endemic area.
- Laboratory workers handling potentially infected materials.
- In order to be officially recognised, the Yellow Fever vaccination must be administered in an approved vaccination centre and registered on an

international certificate. This certificate is valid from the 10th day after vaccination for 10 years.

CONTRAINDICATIONS

Not for use in children under 6 months of age.

Allergy to any component of the vaccine, especially eggs and egg protein (including ovalbumin).

Vaccination should be postponed in the case of fever, acute illness or chronic disease in evolution.

STAMARIL® should not be administered to the following individuals:

- patients receiving high-dose oral or injectable corticosteroids or other immunsuppressive treatment, including radiation therapy;
- those suffering from malignant conditions such as lymphoma, leukaemia, Hodgkin's disease or other tumours of the reticuloendothelial system, including those in remission who have received chemotherapy within the last 6 months;
- patients with impaired immunological mechanisms, such as severe combined immunodeficiency, symptomatic HIV positive individuals and patients who have had recent bone marrow or other organ transplants.

PRECAUTIONS

Only for subcutaneous or intramuscular injection. Do not inject by intravascular route.

As with other injectable vaccines, appropriate medical treatment and supervision should always be available in cases of anaphylactic reactions. Adrenaline should always be readily available whenever the injection is given.

Provided adequate provision is made for observation and any needed treatment of the patient, individuals with suspected allergy to the vaccine may have a skin test of 0.1mL of vaccine intradermally. If there has been no reaction within 15 minutes, the remainder of the dose (ie. 0.4 mL) can be given subcutaneously.

Care should be taken in administering the vaccine to children under 12 months because of a theoretical risk of encephalitis.

Use in Pregnancy Category B2

Live viral vaccines constitute a theoretical risk to the embryo, especially in the first trimester. Although there is data which shows that several hundred pregnant

women have been vaccinated with yellow fever vaccine without consequences to the developing fetus, it is prudent to avoid vaccinating pregnant women, and to postpone travel to areas where yellow fever is present until after delivery. Pregnant women who must travel to areas where the risk of yellow fever is high should be vaccinated. It is believed that under these circumstances, the theoretical risk for mother and fetus from vaccination is far outweighed by the risk of yellow fever infection.

Use in Lactation

No data exists on the use of Stamaril® during lactation.

Interactions With Other Drugs

To avoid reduction in serological responses:

- Another live vaccine, if not given concurrently with Stamaril®, should be given after four weeks have elapsed.
- Injectable cholera vaccine should be given at a minimum interval of four weeks after Stamaril®; if time does not permit, the vaccines should be given simultaneously at separate sites.

ADVERSE REACTIONS

The data used to calculate the rates of common and uncommon adverse reactions have been derived from clinical trials, whereas the rare and very rare adverse reactions are derived from spontaneous reporting of adverse events. The reactions are listed within body systems and categorised by frequency according to the following definitions:

Common:	< 1/10 and ≥ 1/100 patients
Uncommon:	< 1/100 and ≥ 1/1000 patients
Rare:	< 1/1000 and ≥ 1/10000 patients
Very rare:	< 1/10000

Application Site Disorder

Common:	redness
	induration
	pain
	haematoma

Body As A Whole

Common:	asthenia
	fever
Uncommon:	malaise
	influenza-like symptoms
Very rare:	allergic reaction

Central and Peripheral Nervous System Disorders

Common:	headache
Very rare:	meningo-encephalitis
	meningitis

Gastro-intestinal System Disorders

Uncommon:	nausea
	diarrhoea

Musculo-skeletal System Disorder

Common:	myalgia
Rare:	arthralgia
	abdominal pain
	arthritis

Skin and Appendage Disorders

Rare:	rash
Very rare:	eczema

Haematological

Very rare: lymphadenopathy (associated with the injection site)

The very rare cases of meningitis/meningo-encephalitis have been reported with an incidence of 1 in a million or less, and a causal relationship has not been clearly demonstrated.

DOSAGE AND ADMINISTRATION

A single 0.5 mL dose given by intramuscular or subcutaneous injection provides protection for at least 10 years.

The vaccination schedule is identical for adults and children over 6 months.

The contents of each vial should be carefully rehydrated with the accompanying syringe diluent. After complete dispersion, the vaccine is withdrawn back into the

syringe and is ready for injection. Strict aseptic technique should be employed when rehydrating and withdrawing the reconstituted product back into the syringe. The reconstituted vaccine should be used as soon as possible and must be used within one hour of reconstitution.

PRESENTATION AND STORAGE

1 single dose lyophilised vaccine ampoule + (0.5 mL) diluent syringe.

Store at 2-8°C. Do not freeze. Protect from light.

MANUFACTURED BY

Pasteur Mérieux Sérums & Vaccins

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and

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