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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 immunosuppressive 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 0.1 mL 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
1541, avenue Marcel Mérieux
69280 - Marcy L'Etoile - FRANCE
and
Parc Industriel d'Incarville
BP 101
27100 Val-de-Reuil Cedex - FRANCE

DISTRIBUTOR
Australia:
CSL Limited A.C. N . 051 588 348
45 Poplar Road - PARKVILLE VIC 3052

New Zealand:
CSL (New Zealand) Limited
Level 4, Building 10
666 Great South Road - Central Park, Penrose
Auckland 6 - NEW ZEALAND

Date of Approval by TGA: 9 April 1998
Minor amendment: 23 July 1998

HISTORICAL DOCUMENT ONLY

Document 3

CONSUMER MEDICINE INFORMATION

STAMARIL®

YELLOW FEVER VACCINE (LIVE), STABILISED AUST R 58570

t contains information about STAMARIL®. Please read it carefully and keep it for future reference. mation in this leaflet is only a summary and is not intended to replace advice from your doctor. onsult your doctor or pharmacist if you have any comments or questions.

T IS STAMARIL®?

IL® is a vaccine which causes the body to produce immunity against the Yellow Fever virus. It con- live virus (17D strain) which is similar to the yellow fever virus but does not cause yellow fever. Our owever cannot tell the difference and produce antibodies which are the proteins of the immune system tect us from yellow fever. These can be found in the blood about 7 to 10 days after injection and last t 10 years.

T DOES STAMARIL® CONTAIN?

e contains the 17D strain of yellow fever virus which has been grown in chicken eggs which contain se-causing microorganisms. The eggs have specifically been shown to be free of a particular virus – n leucosis virus. Each dose contains at least 1000 units of virus. Each dose contains lactose, sorbitol, e hydrochloride, L-alanine, sodium chloride, potassium chloride, sodium phosphate, potassium phos- lcium chloride and magnesium sulfate.

T IS STAMARIL® USED FOR?

IL® is used for the prevention of yellow fever. Vaccination is recommended for people who live in or rough infected areas or laboratory workers who handle material which may be infected.

ountries require a valid vaccination certificate for travellers to be allowed entry. The vaccine must be an approved vaccination centre to be registered on an international certificate. This certificate is id 10 days after the injection for 10 years.

O SHOULD NOT HAVE STAMARIL®?

IL® should not be used in:

n under 6 months of age,

e allergic to any part of the vaccine,

- people whose immunity is reduced.
- people who have a fever.
- people who are pregnant.
- people having cholera or certain typhoid injections on the same day.

BEFORE YOU HAVE YOUR STAMARIL® INJECTION - YOU SHOULD TELL YOUR DOCTOR IF:

- you may be allergic to any part of the vaccine (eggs).
- you are pregnant.
- you are breastfeeding.
- you have any illness.
- you are taking any medication.
- you are taking any medicines and what they are.

SIDE EFFECTS OF STAMARIL®

As with any medicines some side effects may occur.

Reactions at the site of injection are uncommon and include redness, tenderness, pain and swelling. Rarely the glands under the arm can swell.

People can occasionally get a mild fever. This usually happens within one week of the injection and can be simply treated. Rarely, people can get a higher fever with stiffness, tiredness and headache. This happens between 4 to 7 days after injection.

Very rarely, abnormalities of the central nervous system have been reported after vaccination particularly in children under 12 months but these may not be due to the vaccine.

Always tell your doctor if you have any unpleasant effects after receiving yellow fever vaccine.

THE DOSE OF STAMARIL®

STAMARIL® comes as a freeze-dried powder which is dissolved in the solution in the accompanying syringe.

The solution (0.5 mL) is then given into the muscle or below the skin. The dose is the same for all ages.

OVERDOSAGE

There are no reports of overdosage.

STORAGE

STAMARIL® should be stored between 2°C to 8°C (in the fridge).

It should not be used after the expiry date on the package.

WHERE CAN I GET MORE INFORMATION?

You can get more information from your doctor or pharmacist.

STAMARIL® IS MANUFACTURED BY:

Pasteur Mérieux Sérums & Vaccins
1541, avenue Marcel Mérieux
69280 - Marcy L'Etoile - FRANCE
and
Parc Industriel d'Incarville
BP 101
27100 Val-de-Reuil Cedex - FRANCE

DISTRIBUTOR:

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CSL Limited A.C.N . 051 588 348
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Date of Leaflet: July 1998

Item code n° 07721001A

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