STAMARIL / powder and solvent for suspension for injection\ סטמריל

רופא/ה נכבד/ה ,רוקח/ת נכבד/ה,

חברת מדיצ'י מדיקל בע"מ מודיעה על עדכון העלון לרופא. בהודעה זו מצוינים סעיפים בהם נעשה שינוי מהותי או שינוי המהווה החמרה. עדכונים נוספים אשר אינם מהווים החמרה או שאינם מהותיים, אינם נכללים בהודעה זו (שינוי שהינו הוספה או שינוי ניסוח מסומן כך, מחיקה מסומנת ~~כך~~ והחמרה מסומנת ברקע צהוב).

ההתוויה הרשומה לתכשיר בישראל:

STAMARIL is indicated for active immunization 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 4.2, 4.3 and 4.4 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 recognized, 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 (see Section 4.2).

עדכונים מהותיים נעשו בסעיפים הבאים בעלון לרופא:

[...]

4 CLINICAL PARTICULARS

[...]

4.1 Posology and method of administration

Posology

[...]

Older people

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 travel to an area where there is current or periodic risk of yellow fever transmission (see Sections 4.4 and 4.8).

[...]

4.2 Contraindications

[...]

- Immunosuppression, whether congenital~~, idiopathic~~ or acquired. This includes individuals receiving immunosuppressive therapies such as ~~a result of~~ treatment with high-dose systemic ~~steroids (greater~~corticosteroids (e.g. daily dose of 20 mg or 2 mg/kg body weight of prednisone or equivalent for 2 weeks or more or daily dose of 40 mg or more of prednisone for more than ~~the standard dose of topical or inhaled steroids),~~one week), any other medicinal products including biologicals with known immunosuppressive properties, radiotherapy ~~or,~~ cytotoxic drugs or any other condition which may result in immunocompromised status.

  […]

4.3 Special warnings and precautions for use

[...]

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 (see Section 4.8). To date most of cases of YEL-AND have been reported in primary vaccinees with an onset within 30 days of vaccination. The risk appears to be higher in those aged over 60 years and below 9 months of age (including infants exposed to vaccine through breastfeeding) although cases have been also reported in other age groups. Congenital or acquired immunodeficiency has also been recognized as a ~~potential risk factor (see Section 4.3~~predisposing condition (see Section 4.3). However, cases of YEL-AND have also been reported in individuals with no identified risk factors. Vaccinees should be instructed to seek medical attention if they experience after vaccination any symptoms suggestive of YEL-AND such as high fever with headache or confusion, personality change or if they experience extreme tiredness, stiff neck, fits, loss of movement or feeling in part or all of the body, and they should also be reminded to inform their health care professional that they received yellow fever vaccine (see Section 4.8).

Yellow Fever Vaccine-Associated Viscerotropic Disease (YEL-AVD)

Very rarely, YEL-AVD resembling fulminant infection by wild-type virus has been reported following vaccination (see Section 4.8). The mortality rate has been around 60%. To date, most of cases of YEL-AVD have been reported in primary vaccinees with an onset within 10 days of vaccination. The risk appears to be higher in those aged over 60 years although cases have also been reported in other age groups. ~~History of thymus dysfunction has also been recognized as a potential risk factor (see Section 4.3~~Thymectomy or history of thymus dysfunction have also been recognized as predisposing conditions (see Section 4.3). However, cases of YEL-AVD have also been reported in individuals with no identified risk factors. Vaccinees should be instructed to seek medical attention if they experience after vaccination any symptoms suggestive of a YEL-AVD such as pyrexia, myalgia, fatigue, headache or hypotension, as these can potentially progress quickly to liver dysfunction with jaundice, muscle cytolysis, thrombocytopenia, and acute respiratory and renal failure, and they should also be reminded to inform their health care professional that they received yellow fever vaccine (see Section 4.8).

[...]

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~~are visiting areas where there is an ongoing risk of yellow fever transmission at the time of travel. Countries designated by WHO as where vaccination is not generally recommended, or not recommended, should be considered as not representing a significant and unavoidable risk (refer to updated WHO list of countries with risk of yellow fever transmission) (see above and Section 4.8).

[...]

4.4 Interaction with other medicinal products and other forms of interaction

[...]

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), (see Section 4.3).~~immunosuppressive therapies such as high-dose systemic corticosteroids (e.g. daily dose of 20 mg or 2 mg/kg body weight of prednisone or equivalent for 2 weeks or more or daily dose of 40 mg or more of prednisone for more than one week), any other medicinal products including biologicals with known immunosuppressive properties, radiotherapy, cytotoxic drugs or any other condition which may result in immunocompromised status (see Section 4.3). If there is uncertainty about the level of immunosuppression, vaccination should be withheld and advice sought from a specialist.

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

4.5 Fertility, pregnancy and lactation

Pregnancy

No animal developmental and reproductive studies have been conducted with STAMARIL and the potential risk for humans is unknown. Data on a limited number of exposed pregnancies indicate no adverse effects of STAMARIL on pregnancy or the health of the fetus/newborn child. Nevertheless, as STAMARIL is a live attenuated vaccine, it should not be given ~~to pregnant women only when~~during pregnancy unless clearly needed and only after careful consideration of the potential risks and benefits. Pregnancy should be avoided for one month following vaccination.

Breastfeeding

As there is a probable risk of transmission of the vaccine virus strain to the infants from breastfeeding mothers, STAMARIL should not be given to nursing mothers unless when clearly needed such as during

an outbreak ~~control, and following an assessment of the risks and benefits (see section 4.4).~~and only if the potential benefits to the mother outweigh the potential risks, including those to the breastfed child (see Section 4.4.). In case vaccination is needed, it is recommended to interrupt breast-feeding for at least 2 weeks following vaccination.

[...]

4.6 Undesirable effects

[...]

Tabulated list of adverse reactions

[...]

System Organ Class	Frequency	Adverse reactions
Infections and infestations	Rare	Rhinitis
	Very rare	YEL-AVD‡
Blood and lymphatic system disorders	Not known	Lymphadenopathy
Immune system disorders	Not known	Anaphylactoid reaction including angioedema
Metabolism and nutrition disorders	Very common	Appetite loss*
Nervous system disorders	Very common	Drowsiness*, Headache
	Uncommon	Dizziness
	Very rare	YEL-AND‡, Seizure, Meningitis aseptic
	Not known	Paresthesia
Gastrointestinal disorders	Very common	Vomiting†
	Common	Nausea
	Uncommon	Abdominal pain
	Rare	Diarrhea
Skin and subcutaneous tissue disorders	Common	Rash
	Uncommon	Pruritus
	Not known	Urticaria
Musculoskeletal and connective tissue disorders	Very common	Myalgia
	Common	Arthralgia
General disorders and administration site conditions	Very common	Irritability*, Crying*, Pyrexia†, Asthenia, Injection site pain/tenderness
	Common	Injection site erythema/redness, Injection site hematoma, Injection site induration; Injection site oedema/swelling
	Uncommon	Injection site papule
	Not known	Influenza-like illness

*Specific to paediatric population, (see Section ***d. Paediatric population***)
‡ For clinical features see Section ***c. Description of selected adverse reactions***
† Very common in toddlers (see Section ***d. Paediatric population***), Common in general population

c. Description of selected adverse reactions

Cases of neurotropic disease (known as YEL-AND), some of which have had a fatal outcome, have been reported to occur within 30 days following vaccination with STAMARIL, and other yellow fever vaccines. YEL-AND may manifest as either encephalitis (with or without demyelination), or as a neurologic disease with peripheral nervous system involvement (e.g. Guillain-Barré syndrome). Encephalitis usually starts with high fever with headache that may progress to include ~~one or more of~~encephalopathy (e.g. confusion, lethargy, ~~encephalitis, encephalopathy and meningitis. Other neurological signs and symptoms have been reported and include convulsion, Guillain-Barré syndrome and~~personality change lasting more than 24 hours), focal ~~neurological~~neurologic deficits, cerebellar dysfunction or seizures. YEL-AND with peripheral nervous system involvement usually manifests as bilateral limb weakness or peripheral cranial nerve paresis with decreased or absent tendon reflexes (see Section 4.4).

Neurologic disease not meeting the criteria for YEL-AND has been reported. Manifestations may include cases of aseptic meningitis or seizure with no associated focal neurologic symptoms. Those cases are usually of mild or moderate severity and resolve spontaneously.

[...]

e. Other special population

[...]

Medical history of thymus dysfunction or thymectomy (see Sections 4.3 and 4.4) ~~has~~have been recognized as ~~a potential risk factor~~predisposing conditions for YEL-AVD.

[...]

קיימים עדכונים נוספים . למידע נוסף יש לעיין בעלון לרופא המעודכן.

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות:

https://data.health.gov.il/drugs/index.html#!/byDrug

וניתן לקבלו מודפס על ידי פניה לבעל הרישום מדיצ'י מדיקל בע"מ, רחוב המחשב 3 נתניה טלפון - 097446170

ירון חסיד,

רוקח ממונה - מדיצ'י מדיקל בע"מ