

Review current ACIP recommendations for yellow fever vaccine and expanded access program protocol criteria for Stamaril

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Objective

- Highlight differences between current ACIP recommendations and Expanded Access Program (EAP) IND protocol for Stamaril

ACIP recommendations for use of yellow fever (YF) vaccine in travelers

- Recommended for persons aged ≥ 9 months who are traveling to or living in areas at risk for YF virus transmission
- Because of rare but serious adverse events (SAE), healthcare providers should vaccinate only persons at risk for exposure to YF virus or who require proof of vaccination for entry
- To minimize risk for SAE, healthcare providers should observe contraindications and consider precautions to vaccination before administering vaccine

Overview of EAP IND protocol for Stamaril

- Stamaril available only at selected clinics through IRB approved protocol
- Persons needing vaccination screened for inclusion and exclusion criteria
- Consent/assent obtained prior to administering Stamaril
- Adverse events possibly related to vaccination and SAE passively collected and reported to Sanofi Pasteur

Contraindications or exclusion criteria common to ACIP recommendations and EAP protocol

Allergy to vaccine component

Age <6 months

Symptomatic HIV or asymptomatic HIV with severe immune suppression*

Thymus disorder

Primary immunodeficiencies

Malignant neoplasms

Transplantation

Immunosuppressive and immunomodulatory therapies

*Severe immune suppression defined as CD4+ counts <200/mm³ or <15% of total lymphocytes for children <6 years

Precautions common to ACIP recommendations and EAP protocol

Pregnancy

Age ≥ 60 years

Asymptomatic HIV with moderate immune suppression*

*Moderate immune suppression is defined as CD4+ counts 200-499/mm³ or 15-24% of total lymphocytes for children <6 years

Difference between current ACIP recommendations and EAP protocol criteria

Asymptomatic HIV infection with no evidence of immune suppression*

- Vaccine recommended for at risk travelers in ACIP recommendations
- Precaution in EAP protocol

Age 6-8 months

- Precaution in ACIP recommendations
- Exclusion criteria for EAP protocol

Breastfeeding

- Precaution in ACIP recommendations
- Exclusion criteria for EAP protocol unless can discontinue for 14 days

*No immune suppression is defined as CD4+ counts $\geq 500/\text{mm}^3$ or $\geq 25\%$ of total lymphocytes for children <6 years

Considerations for persons* who could previously receive YF vaccine but are now excluded under EAP protocol

- Defer travel to risk area
- If travel cannot be avoided, use strict mosquito prevention measures

*Infants aged 6-8 months and breastfeeding women who elect not stop feeding

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

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