

GOVERNMENT OF THE PEOPLE'S REPUBLIC OF BANGLADESH
MINISTRY OF HEALTH & FAMILY WELFARE
DIRECTORATE GENERAL OF DRUG ADMINISTRATION
AUSHAD BHAVAN, MOHAKHALI, DHAKA-1212, BANGLADESH
CERTIFICATE OF REGISTRATION

DUPLICATE

We hereby declare that **Stamaril Prefilled Syringe**, manufactured by **Sanofi Pasteur, Parc Industriel d'Incarville 27100 Val de Reuil France**, Marketing Authorization Holder (MAH) M/S. **Sanofi Pasteur, 14 Espace Henry Vallee, 69007 Lyon, France** and represented by **M/s. Sanofi Bangladesh Limited, Station Road, Tongi, Gazipur-1710, Bangladesh** is registered with Directorate General of Drug Administration and Licensing Authority (Drugs) under Reg. No. **102-4650-011**. The drug as described below is allowed to be imported into Bangladesh under **The Drugs Act. 1940 (XXIII of 1940), The Drug (control) Ordinance, 1982** and **The Drug (Control) (Amendment) Act, 2006** subjected to the provision of import policy published by Government from time to time.

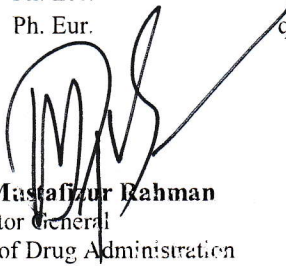
Name of the Product : **Stamaril**
Dosage Form : **Powder and Solvent for suspension for injection in Prefilled Syringe**
Packing : **1 x 1's Powder in vial & 0.5ml solvent in Prefilled Syringe**

Composition: (0.5ml) contains: 0.5ml Solvent in prefilled syringe

<u>Name of ingredients</u>	<u>Specification</u>	<u>Quantity</u>
A Active Ingredient:		
Yellow fever Virus I7 D-204 Strain (Live attenuated)	Ph. Eur.	≥1000 LD ₅₀ units
Excipients:		
B freeze-vaccine conatins:		
Lactose	Ph. Eur.	15.950 mg
Sorbitol	Ph. Eur.	7.975mg
L-histidine HCl	Ph. Eur.	0.833mg
L-alanine	Ph. Eur.	0.362m9
Sodium Chloride	Ph. Eur.	1.630 mg
Potassium Chloride	Ph. Eur.	0.054mg
Disodium Phosphate dihydrate	Ph. Eur.	0.298mg
Potassium dihydrogen phosphate	Ph. Eur.	0.063mg
Calcium Chloride	Ph. Eur.	0.039mg
Magnesium Sulphate	Ph. Eur.	0.029mg
Nitrogen	Ph. Eur.	q.s
C Reconstitution Solvent Contains:		
Sodium Chloride	Ph. Eur.	2.0mg
Water for Injection	Ph. Eur.	q.s to 0.5ml

Registration Date: 16-05-2011
Validity: 15-05-2021

Instructions
To be dispensed only by or
on the prescription of a
registered physician.


Major General Md. Masaffur Rahman
Director General
Directorate General of Drug Administration
&
Licensing Authority (Drugs)
Government of the People's Republic of Bangladesh

06 MAY 2019

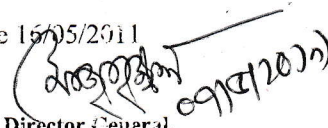
Conditions:

- (1). Labeling should be done in accordance with the provision of the Drugs Act and Rules which require that the name and address of the manufacturer, batch number, manufacturing date, expire date, M.R.P. (Maximum Retail Price) DAR No. (Drug Administration Reg. Number) etc. should be displayed on the label or container and also on the outer cover containing the container
- (2). The registration will be valid for 5 (five) years from its date of issue unless it is revoked, suspended or cancelled earlier.
- (3). The certificate will be treated as cancelled if any violation of conditions and the name or the formula of this product is changed or modified qualitatively or quantitatively without approval of the Licensing Authority.

Memo. No. DA /15-5/102/97/5947

c.c. to: M/S. Sanofi Bangladesh Limited
Station Road, Tongi, Gazipur
Contact. 6/2/A, Segun Bagicha, Dhaka-1000, Bangladesh.

Date 16/05/2011


For Director General,
Directorate General of Drug Administration

