

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

We hereby declare that **Vaxigrip suspension for injection in pre-filled 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. **102-4474-10**. 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 : **Vaxigrip**
Dosage Form : **Suspension for Injection in Pre-filled syringe**
Pack Size : **Pre-filled syringe (0.5ml) with attached needle - box of 1**


Composition:

| <u>Name of ingredients</u> | <u>Specification</u> | <u>Quantity</u> |
|---|----------------------|-----------------|
| A Active Ingredient | | |
| A/Michigan/45/2015 (H1N1)pdm09-like strain | Ph. Eur. | 15 µg of HA |
| A/Singapore/INFIMH-16-0019/2016 (H3N2)-like strain | Ph. Eur. | 15 µg of HA |
| B/Phuket/3073/2013-like strain | Ph. Eur. | 15 µg of HA |
| B Excipient(s) (composition of PBS solution- for 1000ml) | | |
| Buffered saline solution (pH 7.2) | | |
| Sodium Chloride | In-house | 8.00g |
| Potassium Chloride | In-house | 0.20g |
| Disodium Phosphate dihydrate | In-house | 1.15g |
| Potassium dihydrogen phosphate | In-house | 0.20g |
| Water for Injections (WFI) | In-house | Upto 1000ml |

Registration Date: 16-02-2010

Validity: 15-02-2020

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


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

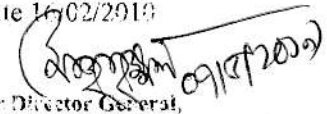
06 MAY 2019**Conditions:**

- (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) D.A.R. 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 /15-5/102/97/1980


Date 16/02/2019

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


 For Director General,
 Directorate General of Drug Administration



This Registration shall remain valid
up to 15-02-2025 unless it is
suspended, Cancelled or revoked earlier.


08.07.2019

Mohammad Mozammel Hossain
Assistant Director
Directorate General of Drug Administration
&
Licensing Authority (Drugs)
Government of the People's Republic of Bangladesh