

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 **Avaxim 80U Pediatric**, manufactured by **Sanofi Pasteur, 1541 Avenue Marcel Merieux, 69280 Marcy l'Etoile, 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. **102-3931-2004**. 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.

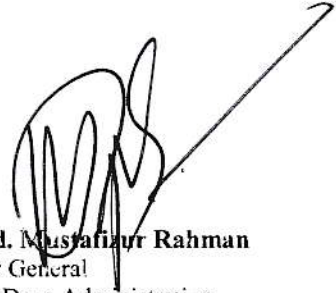
Name of the Product : Avaxim 80U Pediatric
Dosage Form : Suspension for injection
Packing : 0.5ml of suspension, in pre-filled syringe (glass), 1 dose

Composition (Amount(s) per unit dose)

<u>Name of ingredients</u>	<u>Specification</u>	<u>Quantity</u>
<u>Active Ingredient:</u>		
Inactivated Hepatitis A virus	Ph. Eur.	80 antigen units
<u>Excipients:</u>		
Aluminum Hydroxide	Ph. Eur.	0.3 mg
2 phenoxyethanol	Ph. Eur.	2.5 µl
Formaldehyde	Ph. Eur.	12.5ml
Hanks Medium 199	Ph. Eur.	Upto 0.5 ml
Hydrochloride acid or sodium hydroxide for pH adjustment		

Registration Date: 22-06-2004
 Validity: 19-06-2019

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) **6 MAY 2019**
 Government of the People's Republic of Bangladesh

Conditions:

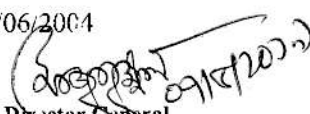
- (1). Labeling should be done in accordance with the provision of the Drugs Act and Rules which require that the name and address of the manufacturer, batch number, manufacturing date, expire date, M.R.P. (Maximum Retail Price) DAR No. (Drug Administration Reg. Number) etc. should be displayed on the 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/ 4979


Date 22/06/2004

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...19-06-2024...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