

Government of the People's Republic of Bangladesh
Ministry of Health and Family Welfare
Directorate of Drug Administration
105-106, Motijheel Commercial Area, Dhaka.



CERTIFICATE OF REGISTRATION

We hereby declare that **Avaxim , Inactivated Hepatitis A Vaccine**, manufactured by ~~Aventis-~~ Pasteur S. A, 58 Avenue Leclerc, 69007 Lyon, France, represented by ~~Aventis~~ ^{Sanoji} ~~Limited~~, Bangladesh is registered with Directorate of Drug Administration and Licensing Authority (Drug) under Registration No. **102-3796-2004**. The drug as described below to be imported into Bangladesh under Drugs Act. 1940 (XXIII of 1940) and Drug (Control) Ordinance 1982 subject to the provision of import policy published by Government time to time.

Name of the Preparation : Avaxim, Inactivated Hepatitis A Vaccine
Form : Suspension for injection.
Packing : 0.5ml of suspension, in pre-filled syringe (glass), 1 dose

Composition (Amount(s) per unit dose)

<u>Active Ingredient:</u>	<u>Specification</u>	<u>Quantity</u>
Inactivated Hepatitis A virus	Ph. Eur.	160 antigen units

Excipients:

Aluminium Hydroxide	Ph. Eur.	0.3 mg
2 phenoxyethanol	Ph. Eur.	2.5µl
Formaldehyde	Ph. Eur.	12.5µg
Hanks Medium 199	Ph. Eur.	up to 0.5ml
Hydrochloric acid or sodium hydroxide for pH adjustment		

This Certificate shall remain valid for five years from its date of issue unless it is revoked, suspended or cancelled earlier

Instructions

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

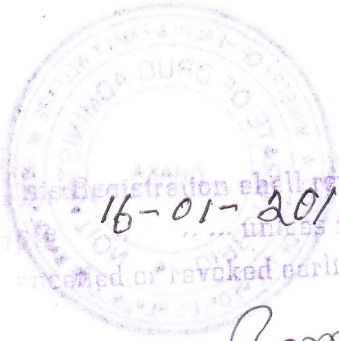
Professor Dr. Abdul Ghani
Director
Directorate of Drug Administration
and
Licensing Authority (Drug)
Govt. of the people's Republic of Bangladesh

Conditions (I) Labeling should contain name and address of the manufacturer, batch number, manufacturing date, expire date, M.R.P. (Maximum Retail Price) DAR No. (Drug Administration Registration Number) (where applicable) etc. should be displayed on the label or container and also on the outer cover containing the container. (ii) The registration will be valid for 05(five) years from the date of issue unless it is revoked, suspended or cancelled earlier. (iii) The certificate will be treated as cancelled if any violation of the conditions and the name or the formula of this product changed or modified qualitatively or quantitatively without approval of the Licensing Authority.

Memo. No. DA/15-5/97(102)/276
C.C. M/S^A Aventis Limited, Bangladesh.
6/2/A, Segun Bagicha, Dhaka-1000

Sanoji
ml → Station Road, Tongi, Gazi pur.

Multane
Date... 19/07/04
For Director
Drugs Administration



This Registration shall remain valid
up to 16-01-2019 unless it is suspended,
cancelled or revoked earlier.

(Signature)
০৬/১/২০০৯

পরিচালক
ঔষধ প্রশাসন কর্তৃক
স্বাক্ষরিত
০৬/১/২০০৯

This Registration shall remain valid
up to 16-01-2019 unless it is suspended
Cancelled or revoked earlier.

(Signature)
24.12.13

Md. Salahuddin
Assistant Director
For Director General
Directorate General of Drug Administration
&
Licensing Authority (Drugs)
Government of the People's Republic of Bangladesh

This registration shall remain valid
up to 16-01-2019 unless it is suspended,
cancelled or revoked earlier.