GOVERNMENT OF THE PEOPLE'S REPUBLIC OF BANGLADESH

MINISTRY OF HEALTH & FAMILY WELFARE
DIRECTORATE GENERAL OF DRUG ADMINISTRATION
AUSHAD BHABAN, MOHAKHALI, DHAKA-1212
www.dgda.gov.bd

CERTIFICATE OF REGISTRATION

We hereby declare that **Prevenar 13 Suspension for Injection in multidose vial,** Manufactured by **Pfizer Manufacturing Belgium NV, Rijksweg 12, 2870 Puurs, Belgium** (site also responsible for batch release in the EU, quality control, primary & secondary packaging) for **Pfizer Europe MA EEIG, Boulevard de la Plaine 17, 1050 Bruxelles, Belgium** represented by **Radiant Export Import Enterprise, Lubdhok, 4th Floor, 474 P, Road No.-3, Sector-12, Uttara, Dhaka-1230, Bangladesh** is registered with Directorate General of Drug Administration & Licensing Authority (Drugs) under Registration Number 366-6663-020. The drug as described below is allowed to be imported into Bangladesh under **The Drugs Act, 1940 (XXIII of 1940) & The Drugs (Control) Ordinance, 1982 and The Drug (Control) Amendment Act, 2006** and subjected to the provision of import policy published by the Government from time to time.

Name of Product : **Prevenar 13**
[Pneumococcal Polysaccharide Conjugate Vaccine, (Adsorbed), 13-valent]
Dosage Form : Suspension for Injection
Pack size : 50 vials (4×0.5ml Dose per vial)
Composition : Each dose (0.5ml) contains

Name of Ingredients	Specification	Quantity (Each 0.5 ml contains)
A. Active Ingredient		
Pneumococcal polysaccharide serotype 1[1]	In House	2.2 µg
Pneumococcal polysaccharide serotype 3[1]	In House	2.2 µg
Pneumococcal polysaccharide serotype 4[1]	In House	2.2 µg
Pneumococcal polysaccharide serotype 5[1]	In House	2.2 µg
Pneumococcal polysaccharide serotype 6A[1]	In House	2.2 µg
Pneumococcal polysaccharide serotype 6B[1]	In House	4.4 µg
Pneumococcal polysaccharide serotype 7F[1]	In House	2.2 µg
Pneumococcal polysaccharide serotype 9V[1]	In House	2.2 µg
Pneumococcal polysaccharide serotype 14[1]	In House	2.2 µg
Pneumococcal polysaccharide serotype 18C[1]	In House	2.2 µg
Pneumococcal polysaccharide serotype 19A[1]	In House	2.2 µg
Pneumococcal polysaccharide serotype 19F[1]	In House	2.2 µg
Pneumococcal polysaccharide serotype 23F[1]	In House	2.2 µg

[1] Conjugated to CRM_{197} carrier protein, adsorbed on aluminium phosphate.
1 dose contains approximately 32 µg CRM_{197} carrier protein and 0.125mg aluminium.

B. Excipients:		
2-Phenoxyethanol	NF, Ph. Eur.	4.0mg
Sodium chloride	USP, Ph. Eur., JP	4.25mg
Succinic acid	NF	0.295mg
Polysorbate 80	NF, Ph. Eur., JP	0.10mg
Water for injections	USP/NF, Ph. Eur.	Qs to 0.5 ml

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

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

Conditions:

1. Labelling should be done in accordance with the provision of The Drugs Act, 1940 and The Rules which require that the name and address of the Manufacturer, batch number, manufacturing date, expiry date, M.R.P. (Maximum Retail Price), DAR No. (Drugs Administration Registration Number) etc. should be displayed on the label of the container and also on the outer cover containing the container.
2. The registration will be valid for 5 (five) years from the date of issue unless it is revoked, suspended or cancelled earlier.
3. The certificate will be treated as cancelled in any violation of the conditions and the name or the formula of this product changed or modified qualitatively or quantitatively without due approval of the Licensing Authority.

Memo No. DA/15-5/13/366/. 201 Dated. 25 / 02 / 2020

c.c.to:
M/s. **Radiant Exoport Import Enterprise**
Lubdhok, 4th Floor, 474 P, Road No.-3,
Sector-12, Uttara, Dhaka-1230, Bangladesh

24.02.20
For Director General
Directorate General of Drug Administration