# 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** Manufactured by **Pfizer Ireland Pharmaceuticals, Grange Castle, Business Park Clondalkin, Dublin-22, Ireland** (also responsible for quality control and primary packaging) & site responsible for Secondary Packaging & Batch release by **Pfizer Manufacturing Belgium NV, Rijksweg 12, 2870 Puurs, Belgium** represented by **M/s JANATA TRADERS, 62/2, Purana Paltan, Dhaka-1000, Bangladesh** is registered with Directorate of Drug Administration & Licensing Authority (Drugs) under Registration No. 213-6697-2020. The drug as described below is allowed to import into Bangladesh under **The Drugs Act. 1940 (XXIII of 1940)** and **The Drug (Control) Ordinance, 1982** subject to the provision of import Policy published by the Government from time to time.

| | |
|---|---|
| Name of Product | : PREVENAR 13 Suspension for Injection |
| Form | : Suspension for Injection in Pre-filled syringe with separate needle |
| Pack Size | : 1 Pre-filled syringe |
| Composition | : Each dose 0.5ml |

Each pre-filled syringe contains:

| Ingredients | Specification | Quantity |
|---|---|---|
| **Active Ingredients:** | | |
| Pneumococcal polysaccharide serotype 1 | Ph. Eur. | 2.2 µg |
| Pneumococcal polysaccharide serotype 3 | Ph. Eur. | 2.2 µg |
| Pneumococcal polysaccharide serotype 4 | Ph. Eur. | 2.2 µg |
| Pneumococcal polysaccharide serotype 5 | Ph. Eur. | 2.2 µg |
| Pneumococcal polysaccharide serotype 6A | Ph. Eur. | 2.2 µg |
| Pneumococcal polysaccharide serotype 6B | Ph. Eur. | 4.4 µg |
| Pneumococcal polysaccharide serotype 7F | Ph. Eur. | 2.2 µg |
| Pneumococcal polysaccharide serotype 9V | Ph. Eur. | 2.2 µg |
| Pneumococcal polysaccharide serotype 14 | Ph. Eur. | 2.2 µg |
| Pneumococcal polysaccharide serotype 18C | Ph. Eur. | 2.2 µg |
| Pneumococcal polysaccharide serotype 19A | Ph. Eur. | 2.2 µg |
| Pneumococcal polysaccharide serotype 19F | Ph. Eur. | 2.2 µg |
| Pneumococcal polysaccharide serotype 23F | Ph. Eur. | 2.2 µg |
| Conjugated to CRM 197 carrier protein and adsorbed on aluminium phosphate (0.125mg aluminium) | | |
| **Excipient(s):** | | |
| Sodium chloride | USP, Ph. Eur., JP | 4.25 mg |
| Succinic acid | NF | 0.295 mg |
| Polysorbate 80 | NF,Ph. Eur.,JP | 0.1mg |
| Water for injection | USP/NF,Ph. Eur. | q.s. to 0.5 mL |

**Major General Md Mahbubur Rahman**
Director General
Directorate General of Drugs Administration
& Licensing Authority (Drugs)
Government of the People's Republic of Bangladesh
Phone: 022222-80803, email: dgda.gov@gmail.com

10 DEC 2020

**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, expiry date, M.R.P (Maximum Retail Price), DAR No. (Drug Administration Registration 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 in any violation of the conditions and if the name or formula of this product changed or modified qualitatively or quantitatively without due approval of the Licensing Authority.

Memo No. DGDA/15-5/2010 (213)/ 5549

Dated: 10/12/2020

CC. **M/s JANATA TRADERS**
62/2, Purana Paltan, Dhaka-1000,
Bangladesh

10.12.20

For Director General
Directorate General of Drug Administration