



**GOVERNMENT OF THE PEOPLE'S REPUBLIC OF BANGLADESH  
MINISTRY OF HEALTH & FAMILY WELFARE  
DIRECTORATE OF DRUG ADMINISTRATION  
105-106 MOTIJHEEL COMMERCIAL AREA,  
DHAKA-1000, BANGLADESH.**

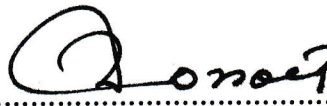
**CERTIFICATE OF REGISTRATION**

We hereby declare that **GARDASIL (Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) Recombinant vaccine)** for I.M. injection, 0.5 mL vial and pre-filled syringe manufactured by **Merck Sharp & Dohme Corp., 770 Sumneytown Pike, P.O. Box 4, West Point, Pennsylvania 19486-0004 USA** represented by **JANATA TRADERS, Healthcare Pharmaceuticals Ltd., 62/2, Purana Paltan, Motijheel, Dhaka-1000, Bangladesh** is registered with Directorate of Drug Administration & Licensing Authority (Drugs) under Registration No. **213-4858-14**..... The drug as described below is allowed to be imported 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** : **GARDASIL (Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) Recombinant vaccine)**  
**Dosage Form** : **Suspension for Injection in 0.5 mL vial and pre-filled syringe**  
**Pack Size** : **1X1 vial pack and 6X1 pre-filled syringe pack**  
**Composition** : **Each dose 0.5ml contains:**

<u>Active Ingredients</u>	<u>Specification</u>	<u>Quantity</u>
Type 6 L1 protein	INN	20µg
Type 11 L1 protein	INN	40 µg
Type 16 L1 protein	INN	40 µg
Type 18 L1 protein	INN	20µg
<b><u>Inactive ingredient(s):</u></b>		
Amorphous aluminium hydroxy-phosphate sulfate adjuvant	INN	225 µg (Aluminum content)
Sodium Chloride	Ph. Eur	9.56 mg
L-histidine	Ph. Eur	0.78 mg
Polysorbate 80	Ph. Eur	50 µg
Sodium Borate	Ph. Eur	35 µg
Water for Injection	Ph. Eur	QS

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

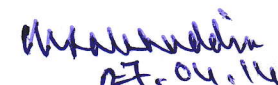
  
 .....  
**Maj. Gen. Md. Jahangir Hossain Mollik**  
**Director General 27 APR 2014**  
**Directorate of Drugs Administration**  
 &  
**Licensing Authority (Drugs)**  
**Government of The People's Republic of Bangladesh**

Conditions: (i) 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.(ii) The registration will be valid for 5 (Five) years from its date of issue unless it is revoked, suspended or cancelled earlier. (iii) 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. **PA/15-5/2010(113)F 451**

Dated: **27-09-14**

Copy to: **Healthcare Pharmaceuticals Ltd.**  
**JANATA TRADERS** Principal office:  
**62/2, Purana Paltan, 3/3A East Rampura, Dhaka-1219.**  
**Dhaka-1000, Bangladesh**

  
**27.04.14**  
**For Director General**  
**Directorate Drugs Administration**

This Registration shall remain valid  
up to 27-04-2024 unless it is suspended  
Cancelled or revoked earlier.

*M. Salahuddin*

13.01.2010

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



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