

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 RotaTeq (Rotavirus Vaccine, Live, Oral, Pentavalent) manufactured by Merck Sharp & Dohme Corp., 770 Sumneytown Pike, P.O. Box 4, West Point, Pennsylvania, 19486-0004 USA represented by ~~JANATA TRADERS, 62/2, Purana Paltan, Motijheel, Dhaka-1000, Bangladesh~~ is registered with Directorate of Drug Administration & Licensing Authority (Drugs) under Registration No. 213-6859-14..... 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.

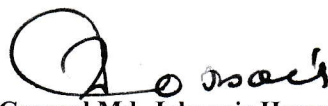
Name of Product : ROTAVIRUS VACCINE, LIVE, ORAL, PENTAVALENT
Dosage Form : Suspension for oral Administration Single Dose
Pack Size : 10X1 pack
Composition : Each 2 mL dose contains the following human-bovine rotavirus reassortants: G1, G2, G3, G4,

<u>Active Ingredients</u>	<u>Specification</u>	<u>Quantity</u>
G1 Reassortant	INN	≥ 2.2 X 10 ⁶ IU/Dose
G2 Reassortant	INN	≥ 2.8 X 10 ⁶ IU/Dose
G3 Reassortant	INN	≥ 2.2 X 10 ⁶ IU/Dose
G4 Reassortant	INN	≥ 2.0 X 10 ⁶ IU/Dose
P1 Reassortant	INN	≥ 2.3 X 10 ⁶ IU/Dose

Inactive ingredient(s):

Sucrose	Ph. Eur.	1080mg
Sodium Citrate Dihydrate	Ph. Eur.	127 mg
Sodium Phosphate Monobasic Monohydrate	USP	29.8 mg
Sodium Hydroxide	Ph. Eur.	2.75 mg
Polysorbate 80	Ph. Eur.	0.17 – 0.86 mg
Rotavirus Diluent & LPKM-3		15% (v/v)

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



Major General 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 DA/15-5/2010/(213)/ 5450

Dated : 27-04-14

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


For Director General
Directorate Drugs Administration

This Registration shall remain valid
up to ~~27-09-2024~~ unless it is suspended
Cancelled or revoked earlier.

Md. Salahuddin

13.01.2016

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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registered physician.

Md. Salahuddin
13.01.2016