



Therapeutic Indications: nimotuzumab is indicated in the treatment of advanced Squamous Cell Carcinoma of Head and Neck region with concurrent chemotherapy and / or radiotherapy. Pediatric patients with recurrent/refractory high grade malignant astrocytoma as monotherapy treatment of adult patients with Glioblastoma multiforme, with concurrent radiotherapy



Republic of Cuba
Ministry of Public Health

CENTER FOR THE STATE CONTROL OF THE QUALITY OF THE MEDICAMENTS

With legal basis on the article 102 of the Law No. 41 of 1983 from the Ministry of Health and once the requirements prescribed in the Regulation for the Medicinal Sanitary Registration of the Republic of Cuba, and on the Requirements for the Inscription, Renovation and Modification of the Human Medicinal Drugs Registry, it is notified the present:

CERTIFICATE OF SANITARY REGISTRATION

Inscription Renovation Modification

Name of the Product: CIMAher®
(Humanized Monoclonal Antibody anti Epidermal Growth Factor Receptor (EGFR))

Pharmaceutical Form: Injection i.v

Entitled, Country: Center of molecular immunology (CIM), Cuba

Manufacturer: Center of molecular immunology (CIM), Cuba

Registry No. 1745

Registry Inscription date: February 19th, 2002

Registry Renovation date: NP

Registry Modification date: October 8, 2007

Registry Expiration date: February, 2010

DESCRIPTION OF MOEDIFICATION

Extension of the Therapeutic indications:

- Patients with advanced head and neck tumors
- Pediatric patients with recurrent/refractory high grade malignant astrocytoma
- Adult patients with Glioblastoma multiforme