PUBLIC ASSESSMENT SUMMARY REPORT

BARYCELA inj., Live Attenuated Varicella Vaccine

GC Biopharma Corp., Republic of Korea

What is BARYCELA inj., Vaccine?

BARYCELA inj., Vaccine is the GC Biopharma Corp., Republic of Korea trade name for live, attenuated varicella-zoster virus vaccine (MAV/06 Virus strain). MAV/06 virus strain was isolated from domestically infected patient with varicella-zoster virus. The stain shows the biological characteristics typical to the varicella-zoster virus. The vaccine is prepared in MRC-5 cell line.

BARYCELA inj., Live Attenuated Varicella Vaccine is a white lyophilized formulation for injection contained in a colorless and transparent vial which appears colorless or light-yellow liquid when dissolved with the enclosed solvent, sterile Water For Injection (WFI).

The vaccine is administered subcutaneously, and it is presented in a 2 mL glass vial of Borosilicate, EP Type Ⅰ clear glass, with a pharmaceutical grade rubber stopper made out of butyl rubber, with a cap made of aluminium-plastics combinations.

The vial bears a Vaccine Vial Monitor (VVM) type 7 affixed on the vial vaccine label.

The Vaccine single-dose vial presentation consists of the following composition per 0.5mL dose:

Components	Quantity (per 0.5 mL)
Active ingredient	
Live attenuated varicella virus (Virus strain: MAV/06, cell line: MRC-5)	≥ 3,800 PFU
Diluent	
Water for injections	0.7 mL
Excipients	
Sucrose, Potassium dihydrogen phosphate, Dibasic sodium phosphate hydrate, Sodium L-glutamate hydrate, L-cysteine, Glycine, Disodium edetate hydrate, Urea, Gelatin	

The shelf-life of Varicella Vaccine Live is 24 months at storage conditions 2 – 8°C.

The vaccine is required reconstitution prior to administration with 0.7 mL of Diluent – Sterile WFI. The sterile WFI is clear, colourless liquid of one single dose presented in glass vial (Borosilicate glass), with a pharmaceutical grade rubber stopper made out of butyl rubber.

The shelf-life of the Diluent is 36 months with storage conditions 2 – 8°C (as the diluent packed and accompany with the vaccine).

The manufacture of bulks, formulation and filling occur in the facilities of GC Biopharma Corp., Republic of Korea.

What is BARYCELA inj., Vaccine used for?

The Live Attenuated Varicella Vaccine is indicated for prevention of varicella in children aged 12 months to 12 years of age.

How is BARYCELA inj., Vaccine used?

The Live Attenuated Varicella Vaccine is a white lyophilized formulation for injection contained in a colorless and transparent vial which appears colorless or light-yellow liquid when dissolved with the enclosed solvent, sterile WFI.

The total volume (approximately 0.5 mL) of reconstituted vaccine is administered as a single dose subcutaneously into the outer aspect of the upper arm (deltoid region), immediately after reconstitution. The reconstituted vaccine must not administer intravascularly or intramuscularly.

What is BARYCELA inj., Vaccine characteristic?

The Live Attenuated Varicella Vaccine must be stored between 2 to 8°C. Under the recommended storage conditions, the vaccine is stable for 24 months from the date of manufacture.

Cold chain volume per dose is 27.5 cm^3 in the secondary carton of single-dose vial presentation accompanying with WFI (2 vials per carton box), and 25.2 cm^3 in the secondary carton of 10 vials presentation accompanying with WFI (20 vials per carton box).

Who is the regulatory authority responsible for its oversight vis a vis WHO?

The BARYCELA inj., Live Attenuated Varicella Vaccine is manufactured by GC Biopharma Corp. and licensed in Republic of Korea. The Republic of Korea is the country of manufacturing.

The Ministry of Food and Drug Safety (MFDS) is the authority responsible for the continuing oversight of this WHO prequalified vaccine.

How has BARYCELA inj., Live Attenuated Varicella Vaccine been studied from the clinical point of view?

The vaccine was studied in a phase 1 single-center, dose block-randomized, single-blind, active-controlled, dose-escalation clinical trial to evaluate the safety and immunogenicity of BARYCELA (MG1111) in healthy adults. This clinical study was designed to escalate the dose from BARYCELA 2,000 PFU to BARYCELA 25,000 PFU. Each cohort included an active control group.

Also, a 2-stage phase 2/3 trial was conducted:
Stage 1: The study was conducted in 3 cohorts (healthy children aged between 12 months and up to 12 years), with each cohort comparing BARYCELA and VARIVAX. This study was randomized, single-blinded, multi-center, and active-controlled. Approximately 100 subjects who met inclusion/exclusion criteria were randomized in the ratio 3:1 per each cohort and received either BARYCELA or VARIVAX.

In total of the 308 subjects that were screened, 300 subjects (100%) were randomized, and 298 subjects (99.3%) completed the study. Among the 300 subjects that were randomized 299 (99.7%) subjects were included in the Safety population and 202 (67.3%) subjects were included in the ITT population. Of these 193 subjects (64.3%) had no important protocol deviation and were therefore included in the PP population.

It was concluded that BARYCELA with the dose levels equal to and higher than 2,000 PFU demonstrated comparable immunogenicity, with good safety profile.

Stage 2: A study in healthy children aged between 12 months and up to 12 years: a randomized, double-blinded, multi-center, multi-national, active-controlled, and non-inferiority trial. Subjects were enrolled in the study and received either BARYCELA or VARIVAX. Subject randomization was stratified by age (12 months to <24 months, 24 months to ⩽12 years) and country.

A total of 529 subjects consented to participate, and 515 subjects were randomized. The total number of subjects analyzed for efficacy were: 478 subjects in Per-protocol (PP) population and 487 subjects in the intent-to-treat (ITT) population. A total of 515 subjects were analyzed for safety.

Overall, the results from this study indicate that BARYCELA demonstrated comparable immunogenicity to VARIVAX. The BARYCELA and VARIVAX were well tolerated and no notable difference in all safety parameters among treatment groups was noted.

BARYCELA data was supported by data from a previous MAV-strain 'parent' vaccine, Suduvax which has been marketed since 1993, including the post licensure safety reports.

Other information about evaluation of BARYCELA inj., Vaccine:

As part of the prequalification process for Live Attenuated Varicella Vaccine Live, the Common Technical Document (CTD) and the responses provided by the manufacturer to observations made by WHO have been reviewed for quality, safety and efficacy by a team of WHO experts, and found to meet WHO requirements of WHO Technical Report Series TRS 848 Annex 1, Varicella vaccine, 1994 (Requirements for varicella vaccine (live).

The manufacturing facility was audited by a WHO team of experts and found to be in compliance with the WHO GMP requirements (WHO TRS 996, Annex 3 2016; TRS 961, Annexes 2, 3 and 6).

WHO has conducted independent testing of batches of the Live Attenuated Varicella Vaccine for critical release parameters in contracted laboratories qualified by WHO for the purpose, and results obtained were in compliance with the quality specifications of the product as specified in the WHO TRS 848 Annex 1, Varicella vaccine, 1994.

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