

BARYCEL A inj. was demonstrated to have a seroconversion rate non-inferior to that of the control vaccine in a multinational phase III clinical trial.

Seroconversion rate (SCR) at 42 days after vaccination

	Conversion criteria	MG1111 ¹ N= 239	Control ² N = 239	Difference	P-value
SCR (%)	FAMA titer ≥1:4	97.91 (95.19, 99.32) ³	99.16 (97.01, 99.90) ³	-1.3 (-4.03, 1.22) ⁴	0.2533
	Sub-analysis Subjects aged 12 M to ≤23 M	97.96 (94.86, 99.44) ³	100.00 (98.11, 100.00) ³	-2.0 (-5.13, 0.27) ⁴	-
	Sub-analysis Subjects aged 24 M to ≤12 Y	97.67 (87.71, 99.94) ³	95.65 (85.16, 99.47) ³	2.0 (-8.21, 12.38) ⁴	-
	FAMA titer ≥1:16	95.65 (93.51, 98.54) ³	98.33 (95.77, 99.54) ³	-1.7 (-4.95, 1.36) ⁴	-

1. Development name of BARYCEL A inj. 2. Varivax 3. Two-sided 95% confidence interval (CI) is calculated using exact binomial method.

4. 95% confidence interval for rate difference is calculated using Newcombe-Wilson score method.



BARYCEL A inj. showed a similar safety profile to that of the control vaccine.

Safety Assessments

	MG1111 ¹ [N=258]		Control ² [N=257]		P-value
	N[%]	event	N[%]	event	
Total AEs	202[78.3]	1109	192[74.7]	1071	0.337
Solicited local AEs	122[47.3]	462	132[51.4]	535	0.355
Solicited systemic AEs	93[36.0]	450	83[32.3]	379	0.370
Treatment-related AEs	160[62.0]	838	162[63.0]	902	0.811
Treatment-related solicited AEs	153[59.3]	789	154[59.9]	864	0.886
Treatment-related unsolicited AEs	41[15.9]	49	27[10.5]	38	0.071
SAEs	29[11.2]	39	21[8.2]	33	0.240
Treatment-related SAEs	3[1.2]	5	4[1.6]	7	0.724

1. Development name of BARYCEL A inj. 2. Varivax.

AE, adverse event; SAE, serious adverse event

Prepare with BARYCEL A inj.
for effective varicella prevention.



Upgraded varicella vaccine through accumulated technology



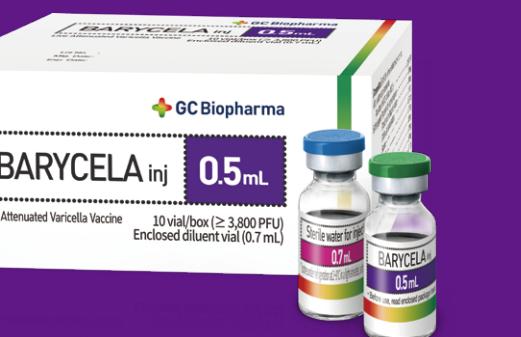
The world's first antibiotic-free varicella vaccine



Vaccine Stability



Improved safety risk through the aseptic processing and single-use systems



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**#VARICELLA
#VACCINE
#BARYCEL A inj.**

#MAV/06 #World 1st Antibiotic-free varicella vaccine #Prevent household infections



GC Biopharma

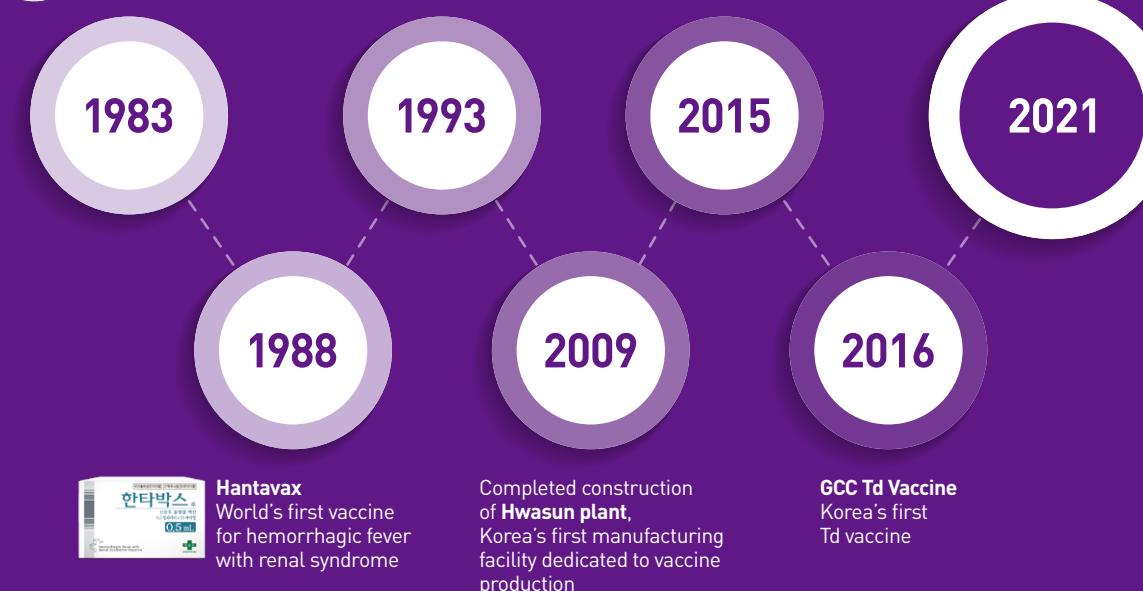
The world's first antibiotic-free varicella vaccine



BARYCELA inj.

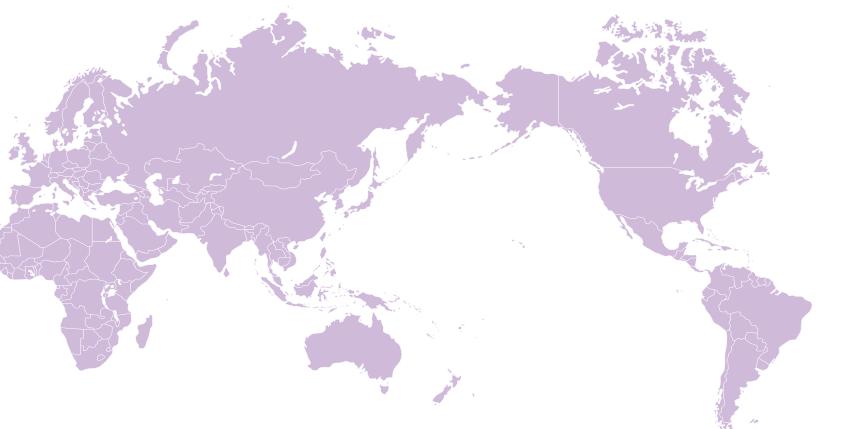
History

GC Biopharma, the leader of Korea's vaccine development



Over the past 28 years, more than 28 million doses of GC Biopharma's varicella vaccine

have been used worldwide and based on our accumulated R&D know-how, an upgraded varicella vaccine, BARYCELA inj. has recently been developed.



28
years

28
million

Over the past 28 years, 28 million doses of Varicella Vaccine-GCC inj. were used in more than 30 countries including Republic of Korea, Brazil, Turkey, Argentina, Saudi Arabia, Vietnam and so on.

BARYCELA inj. is the world's only antibiotic-free varicella vaccine.

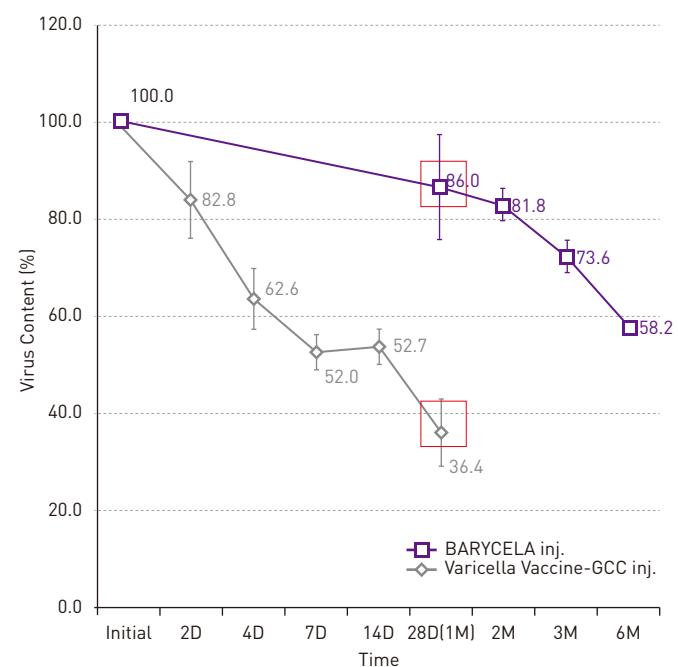


Improved product stability by addition of urea

Accelerated stability test (25.0 ± 2.0 °C/60.0 ± 5.0% RH*)
Varicella Vaccine-GCC inj. vs BARYCELA inj. (1 month) = 36.4% : 86.0%

Formula (product)	SUDUVAX inj. (Varicella vaccine-GCC inj.)	BARYCELA inj.
Sucrose	25 mg	18.21 mg
Glycine	2.5 mg	1.82 mg
Sodium L-glutamate hydrate	0.55 mg	0.40 mg
Gelatin	12.5 mg	8.74 mg
L-Cysteine	0.25 mg	0.18 mg
EDTA or its hydrate	0.25 mg	0.18 mg
Na ₂ HPO ₄ · 12H ₂ O(buffer)	Appropriate amount	1.14 mg
NaH ₂ PO ₄ · 2H ₂ O(buffer)	Appropriate amount	
Potassium phosphate monobasic(buffer)		0.06 mg
Urea		0.87 mg
Volume per dose (mL)	0.5 mL	0.5 mL

*RH, relative humidity



BARYCELA inj. has not only increased virus content, but also significantly improved stability.



Brand name	SUDUVAX inj. (Varicella vaccine-GCC inj.) (First approval date: 05 June 1993)	BARYCELA inj. (First approval date: 02 March 2020)
Virus Strain	MAV/06 (isolated from a Korean patient and attenuated)	MAV/06 (isolated from a Korean patient and attenuated)
Virus content	≥1,400 PFU	≥3,800 PFU
Manufacturing Process	• Manual process • Multi-use system (Closed process, Class 100,000) • Antibiotics contained	• Automated process (Purification, Fill & Finish) • Single-use system (Open process, Class 100) • Antibiotic free • Improved formulation for stability

BARYCELA inj. has improved product safety risk through the introduction of aseptic processing, automated systems, and single-use systems.

