

日本腦炎疫苗

(譯自 **BORYUNG Japanese Encephalitis Vaccine** 英文仿單)

BORYUNG 日本腦炎疫苗係取自經感染日本腦炎中山株病毒株之鼠腦之無菌純化液劑。

成分

每毫升(ml)含：

Active	Inactivated Japanese encephalitis virus.....	1ml
Ingredient	suspension	
Buffer	Dibasic sodium phosphate.....	2.51mg
	Potassium dihydrogen phosphate.....	0.408mg
Isotonic agent	Sodium chloride.....	8.3mg
Surfactant	Polysorbate 80	0.2mg
Stabilizer	Purified gelatin.....	0.2mg
	Disodium edetate.....	0.04mg
Preservative	Thimerosal.....	0.04mg
Solvent	Water for injection.....	q.s.

適應症

預防日本腦炎。

性狀

含有不活化日本腦炎病毒之無色澄清或微白濁液劑。

用法用量

採皮下注射

基礎免疫：經由皮下注射兩劑，每劑 1ml，第一、二劑間隔 1-2 週，第三劑於 12 個月後再給予。(三歲以下幼兒，每次注射 0.5ml)。

追加劑：6 歲和 12 歲各追加一劑(1ml)。

接種注意事項

1. 禁忌

被接種者經問診及視診後，必要時再以聽診、叩診方法了解健康狀況。如果被判斷下列任何一種情況則不宜接種。但被接種者如有感染日本腦炎之危

險，且接種日本腦炎疫苗並不可能產生嚴重疾病時，不在此限。

- 1)發燒或有營養失調者。
- 2)罹患急性嚴重疾病，或活動性心血管疾病、腎臟疾病、肝臟疾病者。
- 3)對疫苗成分有引起過敏之虞者。
- 4)之前接種日本腦炎疫苗有不良反應者。
- 5)接種前一年內，曾發生痙攣者。
- 6)孕婦。
- 7)除上述描述外，其他經評估不適宜接種者。
- 8)對硫柳汞(thimerosal)過敏者。

2. 副作用

- 1)注射後有時會有局部的發紅、腫脹、疼痛、節結等或全身性反應如發燒、惡寒、頭痛、倦怠感，少數有腹瀉、頭昏、關節痛、出疹、嘔吐、胃痛，但通常於 2-3 日內即消失。
- 2)過敏反應可能發生因其中所含的硫柳汞。(有機汞化合物)

3. 注意事項

- 1)施打前應確定疫苗是否混濁、染色或其他物質。如有，切勿使用。
- 2)告知接種對象或監護人接種疫苗須保持穩定，接種部位應保持乾淨，如有發燒或痙攣應立即通知醫生。
- 3)需備妥腎上腺素注射液(1:1000)以應過敏休克或其他過敏症狀之處置。
- 4)全身性蕁麻疹或血管性水腫可能在接種數分鐘後甚至到 17 天發生，多數在接種後 2-10 天發生。
- 5)接種後觀察 30 分鐘是否有全身性蕁麻疹及四肢、臉唇、咽部是否有血管性水腫。

4. 兒童接種注意事項

尚未建立一歲以下兒童接種之安全性與效力。

5. 使用注意事項

- 1)接種器具使用前應以乾熱、高壓、煮沸、ethylene oxide gas 或鈷 60 放射之 γ 射線進行滅菌後，冷卻至室溫。建議不要使用煮沸方法滅菌。
- 2)將欲使用量吸入注射器前，需使用酒精消毒瓶塞，操作過程應遵守無菌避免污染。此外，禁止將針劑溶液裝到另一個容器。
- 3)使用前請務必充分搖晃混合均勻並立即使用。
- 4)接種部位一般在上臂外側，以酒精或碘酒消毒，應避免在同一部位反覆接種。
- 5)應確定不會注射入血管。
- 6)注射針器不能重複使用。

6. 操作注意事項

- 1)勿冷凍以免品質受影響。
- 2)使用前將冷藏的疫苗充分搖晃。

3)開瓶後應當日使用完畢。

儲存條件

請冷儲於攝氏 2-8 度，勿凍結。

有效期限請見包裝標示。

供應

1 毫升×10 瓶裝。

BORYUNG Japanese Encephalitis Vaccine

Inactivated Japanese Encephalitis virus

Boryung Japanese Encephalitis Vaccine is a sterile liquid of purified Japanese encephalitis virus, obtaining from the brain of the mice inoculated intracerebrally with Nakayama strain.

COMPOSITION

Each 1mL contains,

Active ingredient	Inactivated Japanese encephalitis virus	1mL
Buffer	Dibasic sodium phosphate	2.51mg
	Potassium dihydrogen phosphate	0.408mg
Isotonic agent	Sodium chloride	8.3mg
Surfactant	Polysorbate 80	0.2mg
Stabilizer	Purified gelatin	0.2mg
	Disodium edetate	0.04mg
Preservative	Thimerosal	0.04mg
Solvent	Water for injection	q.s.

INDICATIONS :

Prevention from Japanese encephalitis

APPEARANCE

Colorless clear or slightly whitish turbid liquid containing inactivated Japanese encephalitis virus

DOSAGE & ADMINISTRATION :

Subcutaneous injection

Primary immunization :

Two doses of 1mL at the interval of 1-2 week, the third dose of 1mL is given after 12 months. (Inject each dose of 0.5mL for the children below 3 years.)

Booster doses : One dose of 1 mL at each 6 and 12 years of age.

PRECAUTIONS

1. Contraindications

Examine vaccines by asking and seeing, and if necessary, by auscultation and percussion. Then, vaccination is prohibited when vaccines are judged as one of the following cases. But vaccination can be performed in case that there is a danger of infection with Japanese encephalitis virus and no possibility to cause significant disorder by vaccination.

- 1) Febrile patient or the person with malnutrition
- 2) Person with acute, or gradually serious or active cardiovascular, kidney and liver disease
- 3) Person who may manifestly develop allergy by the components of the vaccine
- 4) Person who showed adverse reaction following the injection of this vaccine before
- 5) Person who showed the symptom of spasm within 1 year before vaccination
- 6) Pregnant women
- 7) Person whose state is not enough to be vaccinated besides the above cases
- 8) Person who have the hypersensitivity to thimerosal.

2. Adverse reaction

- 1) There is the possibility of local reaction such as erythema, abscess, sharp pain and nodule formation, systemic reaction such as fever, rigor, headache, fatigue, and rarely diarrhea, dizziness, arthralgia, eruption, vomiting, stomachache. But usually they disappear within 2-3 days.
- 2) Hypersensitivity can be occurred because this drug contains thimerosal (organic forms of mercury).

3. General Caution

- 1) Prior to injection, ought to confirm that there are some turbid, coloration, mixture of an extraneous substance and etc. If there are, do not use.

- 2) Advise the vaccinees or their guardians that the vaccines should keep equilibrium, the injection site is kept clean, and the symptoms of high fever, spasm is reported to doctor as soon as they happen.
 - 3) Epinephrine Injection (1:1,000) must be immediately available should an anaphylactic or other allergic reaction occur due to any component of the vaccine.
 - 4) Generalized urticaria or vascular edema are able to occur in several minutes after vaccination or up to 17 days, and the principle reaction occur within 2-10 days.
 - 5) Watch for 30 minutes after vaccination and the reaction have been characterized by urticaria, often in a generalized distribution, or an angioedema of the extremities, face especially lips and oropharynx .
4. Precaution for Pediatric Use
Safety and efficacy in infant under one year of age have not been established.
5. Caution in Use
- 1) Vaccination apparatus is used after sterilizing by dry heat, high pressure steam, boiling, ethylene oxide gas or gamma ray emitted from Cobalt 60 and then, cooling to room temperature. If possible, avoid sterilizing by boiling.
 - 2) Necessary volume is sucked into syringe after sterilizing stopper and its surrounding with ethanol.
During this procedure, care must be taken to avoid bacterial contamination into the drug solution.
Furthermore, transfer the drug solution to other container for use is prohibited.
 - 3) At the time of administration, shake well to make homogeneous suspension and use immediately.
 - 4) The injection site is usually upper arm lateral and disinfected with ethanol or tincture of iodine. And repeated injections at the same site should be avoided.
 - 5) Confirm the tip of needle should not penetrate blood vessel.
 - 6) Needle should be changed to each vaccine
6. Cautions in Handling
- 1) Do not use frozen vaccine for fear of quality change.
 - 2) Make the refrigerated vaccine room temperature and homogeneous by shaking before use.
 - 3) The vial punctuated once should be used on the day.

STORAGE CONDITION

Keep refrigerated at 2-8. Do not freeze.

Every package and label shows an expiry date.

HOW TO SUPPLIED

1mL × 10 Vials



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