乙型脑炎减毒活疫苗说明书

【药品名称】
通用名称：乙型脑炎减毒活疫苗
商品名称：杰益维
英文名称：Japanese Encephalitis Vaccine，Live
汉语拼音：Yixing Naoyan Jiandu Huoyimiao

【成分和性状】
本品系用流行性乙型脑炎病毒减毒株(SA14-14-2)接种原代地鼠肾细胞，经培养、收获病毒液，加入适宜稳定剂冻干制成。为淡黄色或淡粉色疏松体，复溶后为橘红色或淡粉红色澄明液体。疫苗符合WHO对乙型脑炎减毒活疫苗的要求。

成分	1剂
体积	0.5ml
乙型脑炎活病毒	不低于 5.41gPFU
明胶	4.8mg
蔗糖	21mg
乳糖	21mg
尿素	2.4mg
人血白蛋白	0.9mg
硫酸庆大霉素残留	不高于50ng
牛血清白蛋白残留	不高于50ng
稀释剂成分	灭菌注射用水

【接种对象】
8月龄以上健康儿童及由非疫区进入疫区的儿童和成人。

【作用与用途】
接种本疫苗后，可刺激机体产生抗乙型脑炎病毒的免疫力。用于预防流行性乙型脑炎。

【规格】
复溶后每瓶0.5ml。每一次人用剂量0.5ml，含乙型脑炎活病毒不低于5.4LgPFU。

【免疫程序和剂量】
（1）按标示量加入所附疫苗稀释剂，待疫苗复溶并摇匀后使用。
（2）于上臂外侧三角肌下缘附着处皮下注射。
（3）每次注射0.5ml。现有临床数据显示，8月龄接种1针可以提供至少5年的保护。一些国家的免疫程序建议在2岁时加强1针，以后不再免疫。

疫苗复溶和注射疫苗必须使用无菌注射器和无菌针头。

厂家提供专用稀释剂供疫苗使用，复溶疫苗必须使用厂家提供的专用稀释剂。不能使用其它疫苗稀释剂或其它厂家生产的乙脑减毒活疫苗稀释剂。如使用不正确的稀释剂可能损坏疫苗并导致接种者发生严重不良反应。该专用稀释剂应于2~30℃保存，不得冻结。本疫苗不得使用其它疫苗进行复溶。

【不良反应】
常见不良反应：
（1）一般接种疫苗后24小时内，注射部位可出现疼痛和触痛，多数情况下于2~3天内自行消失。
（2）一般接种疫苗后1~2周内，可能出现一过性发热反应。其中大多数为轻度发热反应，一般持续1~2天后可自行缓解，不需处理，必要时适当休息，多喝开水，注意保暖，防止继发感染；对于中度发热反应或发热时间超过48小时者，可给予物理方法或药物对症处理。
（3）接种疫苗后，偶有散在皮疹出现，一般不需特殊处理，必要时可对症治疗。
罕见不良反应：
重度发热反应：应采用物理方法及药物对症处理，以防高热惊厥。
极罕见不良反应：
（1）过敏性皮疹：一般接种疫苗后72小时内出现荨麻疹，出现反应时，应及时就诊，给予抗过敏治疗。
（2）过敏性休克：一般接种疫苗后1小时内发生。应及时注射肾上腺素等抢救措施进行治疗。
（3）过敏性紫癜：出现过敏性紫癜反应时应及时就诊，应用皮质固醇类药物给予抗过敏规范治疗，治疗不当或不及时有可能并发紫癜性肾炎。
（4）出现血管神经性水肿，应及时就诊。

【禁忌】
（1）已知对该疫苗的所含的任何成分，包括辅料及硫酸庆大霉素过敏者。
（2）患急性疾病、严重慢性疾病、慢性疾病的急性发作期和发热者。
（3）妊娠期妇女。
（4）免疫缺陷、免疫功能低下或正在接受免疫抑制治疗者。
（5）患脑病、未控制的癫痫和其他进行性神经系统疾病者。

【注意事项】
（1）以下情况者慎用：家族和个人有惊厥史者、患慢性疾病者、有癫痫史者、过敏体质者、哺乳期妇女。
（2）开启疫苗瓶和注射时，切勿使消毒剂接触疫苗。
（3）疫苗瓶有裂纹、标签不清或失效者、疫苗复溶后出现浑浊等外观异常者均不得使用。
（4）疫苗瓶开启后应立即使用，如需放置，应置2~8℃于30分钟内用完，剩余均应废弃。
（5）应备有肾上腺素等药物，以备偶有发生严重过敏反应时急救用。接受注射者在注射后应在现场观察至少30分钟。
（6）注射免疫球蛋白者应至少间隔3个月以上接种本品，以免影响免疫效果。
（7）使用其他减毒活疫苗与接种本疫苗应至少间隔1个月。
（8）本品为减毒活疫苗，不推荐在该疾病流行季节使用。
（9）育龄妇女注射本疫苗后，应至少3个月内避免怀

【贮藏】
疫苗于2~8℃避光保存和运输。稀释剂于2-30℃保存和运输。应在标明的有效期前使用。

【包装】
每瓶疫苗1人份，每盒10瓶。
每瓶疫苗提供1瓶配套用稀释剂，稀释剂为灭菌注射用水，用0.5ml稀释剂复溶疫苗。稀释剂由江苏迪赛诺制药有限公司生产。

【有效期】
24个月。

【执行标准】
药品注册标准WS-(ZB-072)-2010
《中华人民共和国药典》三部（现行版）
WHO 有关乙型脑炎减毒活疫苗TRS文件

【批准文号】
国药准字S19980008

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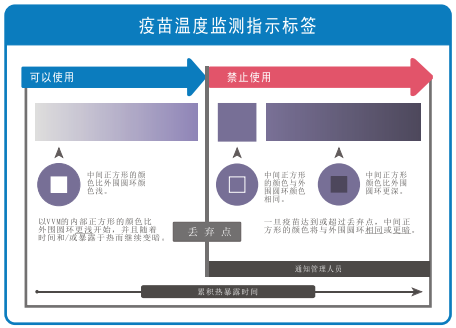

Japanese Encephalitis Vaccine,Live

【DESCRIPTION】
Japanese encephalitis (JE) live vaccine is a preparation of live attenuated JE virus (strain SA14-14-2) grown on the monolayers of primary hamster kidney cell cultures. After cultivation and harvest, appropriate stabilizers are added in the virus suspension, which is then lyophilized. The product looks like a light yellow or light pink crisp cake. After reconstitution, it turns into a clear, orange-red or light pink liquid. The vaccine fulfils WHO requirements for Japanese encephalitis live vaccine.

COMPOSITION	DOSE
VOLUME	0.5mL
Live attenuated JE virus	not less than 5.4 lg PFU
Gelatin	4.8mg
Sucrose	21mg
Lactose	21mg
Carbamide	2.4mg
Human Serum Albumin	0.9mg
Residual gentamicin	not more than 50ng
Residual bovine serum albumin	not more than 50ng
Diluent composition	Sterilized water for injection _（WFI）

【ELIGIBLES】
The vaccine is for active immunization of healthy children older than 8 months of age, as well as children and adults who intend to enter the endemic area from a non-endemic area.

【ACTION AND USE】
The product can induce immunity against JE virus in recipients following immunization. It is used to prevent Japanese encephalitis disease.

【SPECIFICATIONS】
The lyophilized vaccine is reconstituted just before use with sterile diluent (WFI) to obtain 1 dose (0.5mL) of the final vaccine. A single human dose of 0.5mL contains not less than 5.4 lg PFU of live attenuated JE virus.

【ADMINISTRATION AND DOSAGE】
(1) Reconstitute the freeze-dried vaccine with 0.5mL of the enclosed vaccine diluent (WFI), and shake the container thoroughly before use.
(2) Inject the vaccine subcutaneously at the deltoid insertion area of the lateral upper arm.
(3) 0.5mL of vaccine shall be given: The available clinical data showed a single primary dose from 8 months of age can provide at least 5 years of protection. In some countries for programmatic purposes a booster dose at 2 years old is recommended. No more injection is needed henceforth.

A sterile needle and sterile syringe must be used for the reconstitution of the vaccine and for each injection.

The diluent supplied by the manufacturer is specially designed for use with this vaccine. Only this diluent must be used to reconstitute the vaccine. Do not use diluents from other types of vaccines or from other manufacturers. Using an incorrect diluent may result in damage to the vaccine and/or serious reactions to those receiving the vaccine. Diluent must not be frozen but must be stored between 2-30℃ before reconstitution. The vaccine should not be reconstituted with another vaccine.

【ADVERSE REACTIONS】
Common adverse reactions:
(1)Pain and tenderness may occur at the injection site generally within 24 hours after vaccination, which in most cases, can be relieved spontaneously within 2-3 days.
(2)Transient fever may occur generally within 1-2 weeks after vaccination, most of which are mild, and can be relieved spontaneously within 1-2 days without particular treatment. If necessary, the recipients should rest and drink more hot water. Care should be taken to keep warm and prevent secondary infections. The recipients with moderate fever or with fever lasting for more than 48 hours may receive physical therapy or symptomatic treatment.
(3)Occasionally, sporadic skin rashes may occur after vaccination and generally no particular treatment is needed. In case of necessity, symptomatic treatment may be helpful.
Rare adverse reactions:
Severe fever: Physical therapy and symptomatic treatment shall be adopted to prevent febrile convulsion.
Extremely rare adverse reactions:
(1)Allergic rash: Urticaria may occur generally within 72 hours after vaccination. The recipients with urticaria shall promptly receive anti-anaphylactic treatment.
(2)Anaphylactic shock: Anaphylactic shock may occur within one hour after vaccination. The recipients with anaphylactic shock shall receive emergency treatment immediately, including prompt injection of adrenaline.
(3)Allergic purpura: The recipients with allergic purpura shall go to the clinic promptly and receive anti-anaphylactic treatment with corticosteroids in time. If the treatment is improper or delayed, purpuric nephritis can be complicated.
(4)Angioedema: The recipients with angioedema shall receive medical treatment promptly.

【CONTRAINDICATIONS】
The vaccine should not be administered in the following cases:
(1)Subjects with known allergic reactions to any components of the vaccine, including subsidiary materials and antibiotics.
(2)Subjects with acute diseases, severe chronic diseases, and chronic diseases at the stage of acute attack or fever.
(3)Pregnant women.
(4)Subjects with congenital immunodeficiency, immunocompromised subjects or those who are receiving or recently received immunodepressive therapy.
(5)Subjects with encephalopathy, uncontrolled epilepsy or other progressive diseases of nervous system.

【PRECAUTIONS】
(1)The vaccine shall be administered with caution to the subjects with family or individual history of convulsion or those with chronic diseases, history of epilepsy, allergic diathesis or to women who are lactating.
(2)Care should be taken to avoid vaccine contact with disinfectants while opening the container and in the course of injection.
(3)Do not use the vaccine if the container shows abnormalities, such as cracks, illegible labels, exceeding expiry dates, and turbidity after reconstitution.
(4)The vaccine shall be administered immediately after the container is opened, otherwise it shall be kept at 2-8℃ and used within 30 minutes. The remaining vaccine, if any, shall be discarded.
(5)Adrenaline should be available for first aid in case of severe anaphylactic reactions. The recipients shall be observed for at least 30 minutes on site, after injection.
(6)Vaccination should be deferred for at least three months following administration of immunoglobulin.
(7)The vaccine should not be given less than one month before or after administration of other live attenuated vaccines.
(8)As a live attenuated vaccine, the product is not recommended to be administered in the epidemic seasons of Japanese encephalitis.
(9)Women of childbearing age should avoid pregnancy for at least 3 months after immunization.

【STORAGE】
The vaccine should be transported and stored at +2-8℃, protected from light. The diluent should be transported and stored at +2-30 ℃. The vaccine shall be used before the expiry date stated on the label.

【PACKAGING】
The vaccine is presented in boxes of 10 vials, each of them containing 1dose. A vial of diluents (WFI), is provided with each JE vaccine (live) 1-dose vial. A volume of 0.5mL diluent (WFI) is used for reconstitution. Jiangsu Desano Pharmaceutical Co., Ltd manufactures the diluent.

【VALIDITY PERIOD】
24months。

【STANDARD FOR IMPLEMENTATION】
The vaccine satisfies the current WHO recommendations related to the live JE vaccine, Pharmacopoeia of the People's Republic of China (current edition), Volume III and Registration Standard WS-(ZB-072)-2010

【PRODUCT LICENSE NUMBER】
国药准字S19980008

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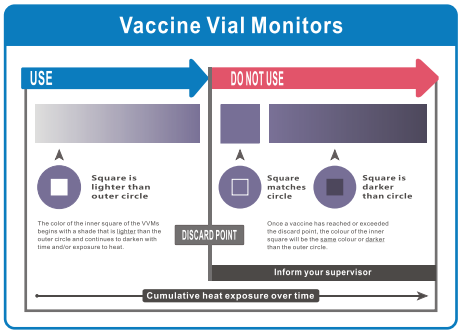

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