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甲型肝炎灭活疫苗说明书

【药品名称】

通用名称: 甲型肝炎灭活疫苗
商品名称: 孩尔来福
英文名称: Inactivated Hepatitis A Vaccine
汉语拼音: Jiaxing Ganyan Miehuo Yimiao

【成份和性状】

本品系用甲型肝炎病毒株接种人胚肺二倍体细胞株,经培养繁殖、收获、提纯、甲醛灭活和氢氧化铝吸附制成。
本品为有微量乳白色沉淀的液体,含有甲肝病毒抗原、氢氧化铝、磷酸氢二钠、磷酸二氢钠、氯化钠、注射用水等。
本品不含防腐剂。

【接种对象】

甲型肝炎易感者。

【作用与用途】

接种本疫苗可刺激机体产生抗甲型肝炎病毒的免疫力,用于预防甲肝病毒感染。

【规格】

成人规格为1.0ml/支(瓶),每次人用剂量为1.0ml,含甲肝病毒抗原500u。
儿童规格为0.5ml/支(瓶),每次人用剂量为0.5ml,含甲肝病毒抗原250u。

【免疫程序和剂量】

免疫程序: 上臂三角肌肌内注射,初次免疫用一支疫苗,间隔6个月加强免疫一支疫苗。
剂量: 16岁以上用成人剂量; 1~15岁用儿童剂量。

【不良反应】

接种疫苗后不良反应轻微,局部不良反应多为疼痛,偶有红肿、硬结;全身不良反应有头痛、发热、恶心等,持续时间不超过24小时,一般可自行缓解。如出现过敏反应,应及时作对症治疗。

【禁忌】

- (1) 患有肝炎或其它严重疾病者。
- (2) 发热性疾病患者应推迟接种。
- (3) 已知对本疫苗任何一种成份过敏者。

【注意事项】

- (1) 注射前充分摇匀。
- (2) 容器有裂纹、疫苗变质或有摇不散的块状物不得使用。
- (3) 有过敏史或家族过敏史者慎用。

【贮藏】

2°C~8°C避光保存、运输,严防冻结。

【包装】

本品为预充式注射器或西林瓶包装,1支(瓶)/盒。

【有效期】

42个月。

【执行标准】

本制品依据国家批准的企业注册标准(编号为: WS4-(S-012)-2006Z)生产和检定。

【批准文号】

成人剂型: 国药准字S20020035
儿童剂型: 国药准字S20020069

【生产企业】

企业名称: 北京科兴生物制品有限公司
SINOVAC BIOTECH CO., LTD.
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INACTIVATED HEPATITIS A VACCINE

[INSTRUCTION]

[COMPOSITION AND DESCRIPTION]

Inactivated hepatitis A vaccine is cultured in human embryo lung diploid cell, followed by harvested, purification, inactivation by formaldehyde and aluminium adsorption.

The vaccine is injectable suspension with trace opalescent sediment, which containing inactivated hepatitis A virus antigen, aluminium hydroxide, sodium dihydrogen phosphate, disodium hydrogen phosphate, sodium chloride, and water for injection.

No preservative in this product.

[OBJECT OF INOCULATION]

People who are at risk of hepatitis A infection.

[THERAPEUTIC INDICATION]

This vaccine can induce body to generate immunoreaction against hepatitis A virus, thus can be used for prevention of infection caused by hepatitis A virus.

[PACK SIZE]

1.0ml/dose/syringe(vial) containing 500 u of HAV antigen for adult use.
0.5ml/dose/syringe(vial) containing 250 u of HAV antigen for junior use.

[ADMINISTRATION AND DOSAGE]

ADMINISTRATION: Intramuscular injection in the deltoid region. The standard primary immunization consists of two doses, the 1st dose is at the selected date, the 2nd dose will be at 6 months later(i.e. 0,6 month schedule)

DOSAGE: 500u/1.0ml is recommended for adults and adolescents 16 years of age and above, 250u/0.5ml is recommended for children between 1 and 15 years old.

[ADVERSE EFFECTS]

The adverse effects of Healive are rare and mild. The most commonly reported adverse events were reaction at the injection site, including pain, redness and nodule and systematic adverse reactions including headache, fever, nausea, most of which can be self-recovered within 24 hours without any treatment. Expectant treatment should be performed immediately if anaphylaxis occurs.

[CONTRAINDICATIONS]

- (1)The vaccine is contraindicated for patient suffering from hepatitis or other severe diseases.
- (2)The vaccination should be postponed for patient with a febrile illness.
- (3)The vaccine is contraindicated in case of hypersensitivity to any one of the vaccine's components.

[PRECAUTIONS]

- (1)Shake before use.
- (2)Do not use in the case that there is any crack in the syringe(vial), the vaccine is degenerative, or there is big masses that can not be dispersed by shaking.
- (3)This vaccine should be used cautiously for patient with hypersensitive history or family hypersensitive history.

[STORAGE]

Store or transport between +2°C and +8°C, protect from light, do not freeze.

[PACKAGE]

Syringe or vial, pack of 1.

[SHELF LIFE]

42 months.

[QUALITY CRITERION]

Healive complies with the authorized requirement(WS4-(S-012)-2006Z).

[AUTHORIZED NUMBER]

Adult:Guo Yao Zhun Zi S20020035
Junior:Guo Yao Zhun Zi S20020069

[MANUFACTURING ENTERPRISE]

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