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SINOVAC

甲型肝炎灭活疫苗(人二倍体细胞)说明书

请仔细阅读说明书并在医师指导下使用

【药品名称】

通用名称:甲型肝炎灭活疫苗(人二倍体细胞)

商品名称:孩尔来福®

英文名称:Hepatitis A Vaccine (Human Diploid Cell), Inactivated

汉语拼音:Jiaxing Ganyan Miehuo Yimiao (Ren Erbeiti Xibao)

【成分和性状】

本品系用甲型肝炎病毒株接种人二倍体细胞2BS株,经培养、收获、病毒纯化、灭活和铝吸附制成。为微乳白色混悬液体,可因沉淀而分层,易摇散。

主要成分:灭活的甲型肝炎病毒

辅料: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】

本疫苗适用于1岁以上甲型肝炎易感者。

【作用和用途】

接种本疫苗可刺激机体产生抗甲型肝炎病毒的免疫力,用于预防甲型肝炎。

【规格】

每支(瓶)0.5ml或1.0ml。每1次成人用剂量为1.0ml,含甲肝病毒抗原500u;每1次儿童用剂量为0.5ml,含甲肝病毒抗原250u。

【免疫程序和剂量】

(1)上臂三角肌肌内注射。

(2)16岁及以上用成人剂量,1~15岁用儿童剂量。初次免疫接种1剂疫苗,间隔6个月加强免疫1剂疫苗。

【不良反应】

常见不良反应:

接种疫苗后,少数人可能出现轻度发热反应,局部疼痛、红肿,一般在72小时内自行缓解。

偶见不良反应:

疲劳乏力,头痛,头晕,呕吐,咳嗽。

罕见不良反应:

(1)局部硬结,1~2个月即可吸收。

(2)偶有皮疹出现,不需特殊处理,必要时对症治疗。

(3)恶心、腹痛、腹泻。

(4)咽痛。

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治疗,治疗不当或不及时有可能并发紫癜性肾炎。

(4)血小板减少性紫癜。

【禁忌】

(1)已知对该疫苗所含任何成分,包括辅料、甲醚以及硫酸庆大霉素过敏者。

(2)妊娠期妇女。

(3)患急性疾病、严重慢性疾病、慢性疾病的急性发作期、发热者。

(4)患未控制的癫痫和其他进行性神经系统疾病者。

【注意事项】

(1)注射前充分摇匀。

(2)有以下情况者慎用: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、既往使用本品出现严重过敏反应者。

(3)疫苗瓶有裂纹、标签不清或失效者、疫苗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。

(5)注射人免疫球蛋白者应至少间隔1个月以上接种本疫苗,以免影响免疫效果。

(6)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。

(7)严禁冻结。

【贮藏】于2~8℃避光保存和运输。

【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《中华人民共和国药典》2020年版和国家批准的企业注册标准(编号为:YBS00072017)生产和检定。

【批准文号】

1.0ml/支(瓶)(成人剂型):国药准字S20020035

0.5ml/支(瓶)(儿童剂型):国药准字S20020069

【上市许可持有人】

名称:北京科兴生物制品有限公司

地址:北京市海淀区上地西路39号

电话:400-898-2688

【生产企业】

企业名称:北京科兴生物制品有限公司

生产地址:北京市海淀区上地西路39号(原液),北京市昌平区中关村科技园区昌平园智通路15号(半成品、成品生产及检定)

邮编编码:100085,102200

电话号码:400-898-2688

传真号码:86-10-62966910

网 址:www.sinovac.com

孩尔来福®

Healive®

甲型肝炎灭活疫苗

210mm

SINOVAC

Revised: 11 March, 2022

HEPATITIS A VACCINE (HUMAN DIPLOID CELL),INACTIVATED

【INSTRUCTION】

【 Name of the Medical Product 】

Generic Name: Hepatitis A Vaccine (Human Diploid Cell), Inactivated

Trade Name: Healive®

【 Composition and Description 】

Healive®, inactivated hepatitis A vaccine is derived from hepatitis A virus cultured in human diploid cell, followed by harvest, purification, inactivation by formaldehyde and aluminium adsorption. Healive® is a purified sterile suspension.

Active Ingredient: Inactivated hepatitis A virus antigen

Excipients: Aluminium hydroxide, sodium dihydrogen phosphate, disodium hydrogen phosphate, sodium chloride, and water for injection. No preservative in Healive®.

【 Target Groups For Vaccination 】

Susceptible people aged over 12 months.

【 Therapeutic Indication 】

Healive® can induce body to generate immunoreaction against hepatitis A virus, and can be used for prevention of infection caused by hepatitis A virus.

【 Strength 】

Each package contains 0.5ml or 1.0ml. Single dose of 1.0ml containing 500u is for adult use. Single dose of 0.5ml containing 250u is for junior use.

【 Administration and Dosage 】

(1) Healive® should be administered by intramuscular injection in the deltoid region.

(2) Healive® 1.0 ml dose is indicated in susceptible adults and adolescents of 16 years of age and above, and 0.5 ml dose in children from 1 to 15 years old. A second dose (booster) should be given 6 months after the first dose.

【 Adverse Reactions 】

Common adverse reactions:

A few adverse reactions will happen, including pain, redness, slightly fever after vaccination, which can be self-recovered within 72 hours without any treatment.

Uncommon adverse reactions:

Fatigue, headache, dizziness, vomiting, coughing.

Rare adverse reactions:

(1) Local reaction such as nodule will be self-recovered in one or two months.

(2) Rash occurs occasionally and needs no treatment and can be treated symptomatically if necessary.

(3) Nausea, abdominal pain, diarrhea.

(4) Sore throat.

Extremely rare adverse reactions:

(1)Anaphylactic erythra: Urticaria could happen within 72 hours after vaccination, which needs medical treatment of antianaphylaxis.

(2)Anaphylactic shock: could happen within one hour after vaccination, which needs first-aid measures such as the injection of adrenalin.

(3)Allergic purpura: needs medical treatment, such as corticosterone for antianaphylaxis. It could induce the associated anaphylactoid purpura nephritis(APN) if no proper or timely treatment.

(4)Thrombocytopenic purpura.

【 Contraindication 】

(1) People who is allergic to any component of vaccine, including excipients, formaldehyde and gentamycin sulfate.

(2) Women during pregnancy.

(3) People who suffer acute diseases, serious chronic disease, acute paroxysm of any chronic disease, fever.

(4) People who have un-controlled epilepsy or other nervous system disease.

【 Precautions 】

(1) Shake well before use.

(2) The product should be used with caution for people who or whose family has the history of convulsion or epilepsy, who has chronic disease or epilepsy history, who suffers from allergies and who had serious allergic reactions during previous use of the product .

(3) Do not use the product if any crack of the container, unclear label, abnormal appearance like foreign matter, or out of expiry date.

(4) This product should be used immediately after opening.

(5) The people who injected with human immunoglobulin should vaccinate this product one month later to avoid affecting immune effect.

(6) Adrenalin and other first aid medicine should be prepared at the vaccination place, in case of serious allergy reaction. The people after vaccination should not leave until 30 minutes after vaccination.

(7) Do not freeze.

【 Storage 】

Store or transport between +2℃ and +8℃, and protect from light.

【 Package 】

Pre-filled syringe or vial. The package unit is one syringe or one vial.

【 Shelf Life 】

42 months.

【Authorization No. 】

Adult: Guo Yao Zhun Zi S20020035

Junior: Guo Yao Zhun Zi S20020069

【Manufacturer 】

SINOVAC BIOTECH CO., LTD.

Address:

For Bulk: No. 39 SHANGDI WEST Road, Haidian District, Beijing, 100085, P.R.China.

For Final Bulk and Final Product: No. 15, ZHITONG Road, Changping Science Park, Changping District, Beijing, 102200, P.R.China.

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Website: www.sinovac.com

孩尔来福®

Healive®

甲型肝炎灭活疫苗

包材名称：说明书（甲型肝炎灭活疫苗（人二倍体细胞）注射器）

尺 寸：120*210mm