90mm

185mm

核准日期：2020年06月17日
修订日期：2020年07月07日
修订日期：2021年05月28日
修订日期：2021年07月08日

SINOVAC

四价流感病毒裂解疫苗说明书

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：四价流感病毒裂解疫苗
英文名称：Influenza Vaccine (Split Virion), Inactivated, Quadrivalent
汉语拼音：Sijia Liugan Bingdu Liejie Yimiao

【成分和性状】
本品系用世界卫生组织（WHO）推荐的甲型和乙型流行性感冒（简称流感）病毒株，分别接种鸡胚，经培养、收获病毒液，病毒灭活、纯化、裂解后制成，为微乳白色液体。
有效成分：当年使用的各型流感病毒株血凝素，本品每0.5ml含：
A/Victoria/2570/2019(H1N1)pdm09-like virus……15μg 血凝素
A/Cambodia/e0826360/2020(H3N2)-like virus……15μg 血凝素
B/Washington/02/2019(B/Victoria lineage)-like virus……15μg 血凝素
B/Phuket/3073/2013(B/Yamagata lineage)-like virus……15μg 血凝素
辅料：氯化钠、磷酸氢二钠、磷酸二氢钠。

【接种对象】
本品适用于3岁及以上人群；尤其推荐易发生相关并发症的人群，如儿童、老年人、体弱者、流感流行地区人员等。

【作用与用途】
接种本品后，可刺激机体产生抗流感病毒的免疫力，用于预防疫苗相关型别的流感病毒引起的流行性感冒。

【规格】
每瓶0.5ml，每1次人用剂量为0.5ml（成人及3岁以上儿童），含各型流感病毒株血凝素应为15μg。

【免疫程序和剂量】
1.于上臂外侧三角肌肌内注射。
2.于流感流行季节前或期间进行预防接种。3岁及以上人群接种1针，每次接种剂量为0.5ml。使用前摇匀。

【不良反应】
1.本品临床试验
本疫苗在中国境内完成的Ⅰ、Ⅲ期临床试验受试者总数为2380名（3岁及以上人群），其中1220名受试者接种了一剂本品。对本品系统的安全性观察自疫苗接种开始至全程接种后28天，对大部分受试者的长期安全性观察自全程接种后29天至180天。
按照国际医学科学组织委员会（CIOMS）推荐的不良反应发生率的分类：十分常见（≥10%），常见（1%~10%，含1%），偶见（0.1%~1%，含0.1%），罕见（0.01%~0.1%，含0.01%），十分罕见（<0.01%），进行如下描述：
全身不良反应
常见：发热；
偶见：头痛、恶心呕吐、肌肉痛、疲劳乏力、咳嗽；
罕见：腹泻、心悸。
局部不良反应
常见：疼痛、红；
偶见：硬结、肿、瘙痒。
以上不良反应应80.16%为轻度。未发现与本品相关的严重不良事件。
2.同类产品境内外临床试验
除上述不良反应外，在同类产品境内外临床试验中还观察到如下不良反应：
全身不良反应：过敏反应（超敏反应）、关节痛、腹部疼痛或不适、嘈唑、易激惹、食欲下降、寒颤；
局部不良反应：皮疹、瘀斑。
3.同类产品上市后监测
境外同类产品上市后监测获得的额外安全性数据（由规模不详人群自发报告产生，难以准确估计症状的发生率或有效评估症状发生与疫苗使用的相关性）汇总如下：
消化系统：口腔、喉部和/舌头肿胀；
血液及淋巴系统：淋巴结肿大、血小板减少；
感染和侵袭性疾病：咽炎、鼻炎、扁桃体炎；
全身性疾病及给药部位各种反应：注射部位脓肿、注射部位蜂窝组织炎、注射部位发热、胸痛、流感样疾病、全身酸痛；
神经系统疾病、脊髓炎（包括脱脊髓炎和横贯性脊髓炎）、面神经麻痹、格林-巴利综合征、神经炎、感觉异常、头晕、晕厥；
呼吸系统、胸及纵膈疾病：喉痛、支气管痉挛、呼吸困难、呼吸窘迫、鼻漏、喘鸣；
心血管系统：心动过速、血管炎；
内耳前庭系统：眩晕；
皮肤系统：血管性水肿、红斑、多形红斑、面部肿胀、瘙痒、Stevens-Johnson综合征、出汗、荨麻疹；
眼部：结膜炎、眼睛疼痛、眼睛发红、眼睛肿胀、眼睑肿胀；
免疫系统：过敏性休克、过敏性紫癜、血清病。

【禁忌】
如有以下任一情况，禁用本品，并及时告知医生：
1.已知对本品所含任何成分，包括辅料、甲醛、Triton X-100、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、感冒和发热者。
3.未控制的癫痫和患其他进行性神经系统疾病者，有格林-巴利综合征病史者。

【注意事项】
1. 以下情况者慎用本品：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。
2. 本品针管有裂纹、标签不清或失效者、疫苗出现浑浊、疫苗变质或有絮不散的块状絮状物等外观异常者均不得使用。
3. 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。
4. 免疫抑制剂的应用可降低或抑制疫苗接种后的免疫应答，注射免疫球蛋白者，应间隔1个月以上再接种本疫苗，以免影响免疫效果。
5. 注射后出现任何神经系统反应者，禁止再次使用。
6. 本品严禁冻结。
7. 本品严禁静脉注射。
8. 请放在儿童不易触及处。
9. 注射前充分摇匀。
10.本品不得与其他医疗产品在同一容器内混合后使用。
11.有下列情况请向医生咨询：
(1) 免疫功能低下；
(2) 对本品有其它疑问。

【孕妇及哺乳期妇女用药】
目前尚未获得孕妇及哺乳期妇女使用本品的临床试验数据。若该人群需使用本品，建议与医生共同进行获益/风险评估后决定。

【药物相互作用】
1.与其它疫苗同时接种：本品尚未联合接种其它疫苗对本品免疫原性影响的临床研究。目前尚无数据可以评价本品与其它疫苗联合接种的影响。
2.与其它药物伴随使用：具有免疫抑制作用药物包括免疫抑制剂、化疗药物、抗代谢药物、烷化剂、细胞毒素类药物、皮质类固醇类药物，以及免疫球蛋白等，可能会降低机体对本品的免疫应答。
如正在或近期曾使用过任何其它疫苗或药物，为避免可能的药物间相互作用，接种本品前建议咨询专业医师。

【贮藏】于2~8°C避光保存和运输。

【包装】西林瓶包装，1瓶/盒。

【有效期】12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：YBS00092020）生产和检定。

【批准文号】西林瓶包装：国药准字S20217013

【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

【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号北大生物城（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）
邮政编码：100085，102200
电话号码：86-10-82890088
传真号码：86-10-62966910
企业网址：www.sinovac.com

四价流感病毒裂解疫苗
Influenza Vaccine (Split Virion), Inactivated, Quadrivalent

Revised: 08 July, 2021

SINOVAC

INFLUENZA VACCINE (SPLIT VIRION), INACTIVATED, QUADRIVALENT
【INSTRUCTION】

Please read this instruction carefully and use under the guidance of physicians

【NAME OF THE MEDICAL PRODUCT】
Generic Name: Influenza Vaccine (Split Virion), Inactivated, Quadrivalent

【COMPOSITION AND DESCRIPTION】
This product is derived from the influenza virus recommended by WHO, which is cultured in chicken embryo, followed by harvest, inactivation, purification and disruption. Finally, a slightly opalescent suspension with no foreign particles is obtained.
Active ingredients:
For hemagglutinins of prevalent strains of influenza virus in current year, vaccine of 0.5ml contains:
15μg haemagglutinin of A/Victoria/2570/2019 (H1N1) pdm09-like virus
15μg haemagglutinin of A/Cambodia/e0826360/2020 (H3N2)-like virus
15μg haemagglutinin of B/Washington/02/2019 (B/Victoria lineage)-like virus
15μg haemagglutinin of B/Phuket/3073/2013 (B/Yamagata lineage)-like virus
Excipients include sodium chloride, disodium hydrogen phosphate, sodium dihydrogen phosphate.

【TARGET GROUPS FOR VACCINATION】
The vaccine is approved for use in people aged 3 and above, especially in vulnerable people and high risk population for influenza complications, such as children, the elderly, the weak and people in influenza epidemic areas.

【THERAPEUTIC INDICATION】
This product can induce body to generate immunoreaction against influenza virus and can be used for prevention of infection caused by the influenza virus strain.

【STRENGTH】
Each package contains 0.5 ml liquid. Single dose of 0.5 ml is for adults and children aged over 3 years, containing 15 μg haemagglutinin per type of influenza virus strain.

【ADMINISTRATION AND DOSAGE】
1. Intramuscular injection on deltoid.
2. For prophylactic vaccination during or before influenza pandemic period, adults and children aged over 3 years are administered one 0.5ml dose. Shake well before use.

【ADVERSE REACTIONS】
1. Clinical trials of the vaccine
   The number of subjects enrolled in the Phase I, III clinical trials domestically was 2380 (≥ 3 years old) among which 1220 patients were vaccinated with one dose. The safety observation was started from the day of vaccination, during the whole procedure until day 28 after vaccination. For the majority of the subjects, the long-term safety observation was started from the day 29 to day 180 after vaccination.
   According to the classification of adverse reaction incidence recommended by The Council for International Organizations of Medical Sciences (CIOMS): Extremely Common (≥10%), Common (1%~10%, including 1%), Occasional (0.1%~1%, including 0.1%), Rare (0.01%~0.1%, including 0.01%), Extremely rare (<0.01%), description as follows:
   Systematical adverse reaction
   Common: fever;
   Occasional: headache, nausea and vomiting, muscle pain, fatigue, cough;
   Rare: diarrhea, palpitations
   Local adverse reaction
   Common: pain, redness
   Rare: induration, swelling, itching 80.16% of the above adverse reactions were mild. No severe adverse event related to the product was observed.
2. Domestic and Overseas Clinical trials of generic products
   Except the adverse reactions described above, adverse reactions observed in the domestic and overseas clinical trials of generic products are:
   Systematical adverse reaction: Allergic reactions (hypersensitivity), joint pain, abdominal pain or discomfort, drowsiness, irritability, loss of appetite, chills Local adverse reaction: erythra, ecchymosis
3. Post- marketing surveillance of the generic vaccines
   Except the above information on safety, considering the post-marketing surveillance of the generic products overseas, the following adverse reactions are observed (data was voluntarily reported by uncertain populations; the incidence could not be assessed accurately; and the relation with vaccination could not be judged effectively).
   Digestive system: swelling of the mouth, throat and/or tongue;
   Blood and lymphatic system: enlarged lymph nodes, thrombocytopenia;
   Infection and invasive diseases: pharyngitis, rhinitis, tonsillitis;
   Systemic diseases and reactions at the injection site: abscess at the injection site, cellulitis at the injection site, fever at the injection site, chest pain, influenza-like illness, and aches and pains all over the body;
   Nervous system: convulsion, myelitis (including encephalomyelitis and transversal myelitis), facial palsy, guillain-barre syndrome, neuritis, paresthesia, dizzy, syncope;
   Respiratory, chest and mediastinal diseases: asthma, bronchospasm, dyspnea, respiratory distress, rhinorrhea, wheezing;
   Cardiovascular system: tachycardia, vasculitis;
   Vestibular system of inner ear: vertigo;
   Skin system: angioedema, erythema, multiple erythema, facial swelling, itching, Stevenson-Johnson syndrome, sweating, urticaria;
   Eye: conjunctivitis, eye pain, eye redness, eye swelling, eyelid swelling;
   Immune system: anaphylactic shock, anaphylactic purpura, serum disease.

【CONTRAINDICATION】
In case of any of the following conditions, it is forbidden to use this product and inform the doctor in time.
1. People who is allergic to any component of the vaccine, including excipients, formaldehyde, Triton X-100 and gentamycin.
2. People who suffers acute diseases, serious chronic disease, acute paroxysm of any chronic disease, cold and fever.
3. People who has un-controlled epilepsy or other progressive nervous system disease, and guillain-barre syndrome.

【PRECAUTIONS】
1. This product should be used with caution for people who or whose family has the history of convulsion or epilepsia, chronic disease and allergy symptoms.
2. Do not use the product in the case that there is any crack or unclear label in the container, the product is out of expiry date or there is abnormal appearance, for example, the vaccine is turbid or degenerative, or there is big mass that cannot be disappeared by shaking.
3. 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.
4. Application of immunosuppressors may decrease or inhibit immunization reactions. People administrated globulin should be vaccinated the vaccine 1 month later so as not to affect the immune effect.
5. People who has any reaction of nervous system after the vaccination of this product, is not able to be vaccinated again.
6. Must not be frozen.
7. This vaccine is strictly prohibited for intravenous injection.
8. This product should be stored out of the reach of children.
9. Shake well before use.
10. The product should not be mixed with other vaccines in the same container.
11. Please seek medical advice if:
   1) You have defected immune function.
   2) You have other questions about this product.

【MEDICATION FOR PREGNANT AND LACTATING WOMEN】
No clinical trial data on the use of this product is available for pregnant and lactating women. If this group of people needs to use this vaccine, it is recommended to make a decision after the benefit/risk assessment together with a doctor.

【DRUG-DRUG INTERACTIONS】
1. Vaccinated simultaneously with other vaccines: No combine vaccination effect to the immunogenicity was studied in clinical trials. No existing evidence for evaluation of the influence of combine vaccination.
2. Vaccinated in accompany with other drug: Application of immunosuppressive drug such as immunosuppressor, chemotherapeutics, anti-metabolites, alkylating agents, cytotoxic drugs, cortiosteroid drugs and immunoglobulin, may decrease the immunization reactions.
   Please seek medical advice if other vaccine or drugs are being used currently or have been used recently in order to avoid potential drug-drug interactions.

【STORAGE】Store and transport between +2°C and +8°C, and protect from light.

【PACKAGE】Vial. The package unit is one vial.

【SHELF LIFE】12 months.

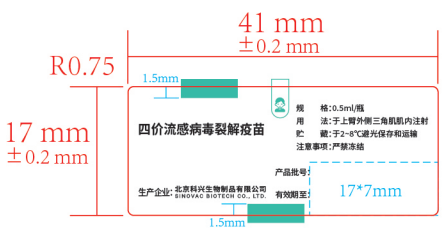
【DRUG APPROVAL NO.】For vail: GuoYaoZhunZi S20217013

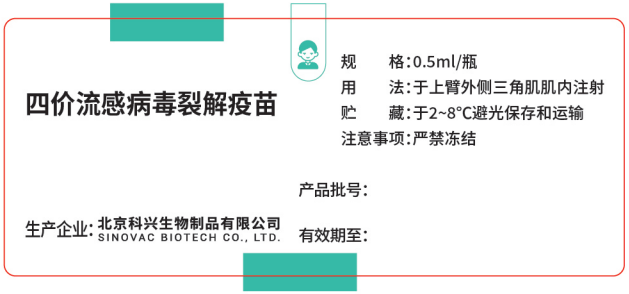
【MANUFACTURER】
Name: SINOVAC BIOTECH CO., LTD.
Address: For bulk: No.39, ShangdiXi Road, Haidian District, Beijing.
For final bulk and final product: No. 15, Zhitong Road, Changping Science Park, Changping District, Beijing.
Postal code: 100085, 102200
Tel.: 86-10-82890088
Fax: 86-10-62966910
Website: www.sinovac.com

四价流感病毒裂解疫苗
Influenza Vaccine (Split Virion), Inactivated, Quadrivalent

客户名称	北京科兴生物制品有限公司	产品名称及版本号	说明书(四价流感病毒裂解疫苗西林瓶) QX-03-01B

客户名称	北京科兴生物制品有限公司	产品名称及版本号	小包装盒(四价流感病毒裂解疫苗成人西林瓶) QCX-01-01B





PANTONE 2239c

K100

荧光标签（四价流感病毒裂解疫苗西林瓶）

225 mm
±0.5 mm

R10

2mm

色条宽4.6mm ±0.3 mm

195 mm
±0.5 mm

1.8mm

2mm

1.8mm

☐ 西林瓶 ☐ 预充式注射器

四价流感病毒裂解疫苗

Influenza Vaccine (Split Virion), Inactivated, Quadrivalent

规　　格：
Strength

包装规格：
Quantity

产品批号：
Lot No.

生产日期：
Mfg. Date

有效期至：
Exp. Date

生 产 商：**北京科兴生物制品有限公司**
Manufacturer：SINOVAC BIOTECH CO., LTD.
地址/Add.：
原　　液：北京市海淀区上地西路39号北大生物城，100085
For Bulk：No.39, SHANGDI WEST Road, Haidian District, Beijing, 100085, P.R.China.
半 成 品 、成 品：北京市昌平区中关村科技园区昌平园智通路15号，102200
For Final Bulk and Final Product：No.15, Zhi Tong Road, Changping Science Park, Changping District, Beijing, 102200, P.R.China.

批准文号：国药准字S20217013（西林瓶包装）、
国药准字S20200010（预充式注射器包装）
Drug Approval No.: GuoYaoZhunZi S20217013 (for vial),
GuoYaoZhunZi S20200010 (for syringe)

电话/Tel.:86-10-82890088
传真/Fax :86-10-62966910
网址/Web.:www.sinovac.com

SINOVAC

2°C～8°C避光保存和运输，严禁冻结。
Store and transport between +2°C and +8°C, and protect from light. Do not freeze.

PANTONE 2239c
M100 Y100 K10
K100

外箱标签（四价流感病毒裂解疫苗）