核准日期：2007年01月16日
修改日期：2008年04月11日

流感病毒裂解疫苗说明书

【药品名称】
通用名称：流感病毒裂解疫苗
商品名称：安尔来福
英文名称：Inactivated Influenza Vaccine (Split Virion)
汉语拼音：Liugan Bingdu Liejie Yimiao

【成份和性状】
本品系用世界卫生组织分发的甲$_1$型、甲$_3$型、乙型流行性感冒病毒当年流行株或相似株分别接种鸡胚，经培养、收获、灭活、裂解和纯化制备而成的裂解疫苗。
疫苗外观为轻微乳白色液体，无异物。
——赋形剂
钠盐：氯化钠、磷酸氢二钠、磷酸二氢钠。
本品不含防腐剂。

【接种对象】
推荐用于成人和6个月以上儿童，特别推荐给易发生相关并发症的人群，如儿童、老年人、体弱者、流行性感冒流行地区人员等。

【作用与用途】
本品免疫接种后，可产生对流行性感冒病毒的保护性抗体，用于预防流行性感冒。

【规格】
儿童规格为0.25ml/支（瓶）。

含抗原：	H_1N_1	7.5μg	血凝素	型别：A/California/7/2009
	H_3N_2	7.5μg	血凝素	型别：A/Victoria/210/2009
	B	7.5μg	血凝素	型别：B/Brisbane/60/2008

成人规格为0.5ml/支（瓶）。

含抗原：	H_1N_1	15μg	血凝素	型别：A/California/7/2009
	H_3N_2	15μg	血凝素	型别：A/Victoria/210/2009
	B	15μg	血凝素	型别：B/Brisbane/60/2008

【免疫程序和剂量】
免疫程序：上臂三角肌肌内注射。成人及36个月以上儿童接种一针。6个月至36个月儿童接种二针，间隔4周。
剂量：成人及36个月以上儿童剂量为0.5 ml/剂量。
6个月至36个月儿童剂量为0.25 ml/剂量。

【不良反应】
本品可能在某些人中引起或轻或重的不良反应。
局部反应：红、肿、痛、硬结。
全身反应：发热、头晕、寒颤、虚弱、出汗、肌痛、关节痛、头痛、瘙痒、皮疹。
上述反应无需治疗，一般1-2天会自行消失。
本品罕有休克、惊厥、一过性肾性脉管炎、神经系统疾病等其它反应，如出现未提到的不适感觉，应及时与医生取得联系。

【禁忌】
下列人群严禁使用本品
发热、急性疾病及感冒者。
慢性疾病急性发作者。
对鸡蛋或疫苗中任何其它成份，特别是卵清蛋白过敏者。
格林巴利综合症患者。

【注意事项】
(1) 容器有裂纹、疫苗变质或有摇不散的块状物不得使用。
(2) 严禁通过血管途径给药。
(3) 请放在儿童不易触及处。
(4) 注射前充分摇匀。
(5) 有过敏史者慎用。
(6) 本品不能与其他疫苗在同一容器内混合后使用。
(7) 同其他疫苗一样，为预防接种后发生罕见过敏反应，应有适当医疗和监护准备。
(8) 免疫抑制剂的应用可降低或抑制疫苗接种后的免疫应答，注射丙种球蛋白者，应间隔1个月以上再接种本疫苗。
(9) 有下列情况请向医生咨询。
免疫功能低下
对庆大霉素过敏者（疫苗制造过程中使用该物质）
对本品有其它疑问
(10) 怀孕期间是否接种，请遵循医生意见。哺乳不是本疫苗的禁忌症。

【贮藏】
2℃～8℃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】
自疫苗配比之日起有效期为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：YBS00242008）生产和检定。

【批准文号】
儿童剂型：国药准字S20053055
成人剂型：国药准字S20053056

【生产企业】
企业名称：北京科兴生物制品有限公司
SINOVAC BIOTECH CO., LTD.
生产地址：北京市海淀区上地西路39号北大生物城
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INACTIVATED INFLUENZA VACCINE (SPLIT VIRION)
【INSTRUCTION】

【COMPOSITION AND DESCRIPTION】
-Inactivated influenza vaccine cultured in eggs, followed by harvested, inactivated, split and purified.
The product is a slightly opalescent suspension with no foreign particles.
Excipients include sodium chloride, disodium hydrogen phosphate, sodium dihydrogen phosphate and water for injection.
No preservative in this product.

【TARGET GROUPS FOR VACCINATION】
Vaccination is recommended for adults and children from six months and above, especially those having high risk of associated complications, such as children, senior citizens, those who are susceptible and those who are in influenza epidemic areas.

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

【PACK SIZE】
The vaccine used for junior is 0.25ml per dose.
Each single junior dose of 0.25ml contains:

H_1N_1	7.5 micrograms of haemagglutinin	A/ California/7/2009
H_3N_2	7.5 micrograms of haemagglutinin	A/ Victoria/210/2009
B	7.5 micrograms of haemagglutinin	B/ Brisbane/60/2008

The vaccine used for adult is 0.5ml per dose.
Each single adult dose of 0.5ml contains:

H_1N_1	15 micrograms of haemagglutinin	A/ California/7/2009
H_3N_2	15 micrograms of haemagglutinin	A/ Victoria/210/2009
B	15 micrograms of haemagglutinin	B/ Brisbane/60/2008

【ADMINISTRATION AND DOSAGE】
Administration: Intramuscular injection on deltoid.
Dosage: Adults and children above 36 months are administered one 0.5ml dose; Children between 6 to 36 months are administered two times, each time 0.25ml dose with the interval of 4 weeks.

【POSSIBLE UNDESIRABLE EFFECTS】
As with all medicinal products this product may cause undesirable effects.
Local reactions: redness, swelling, pain, induration.
Systematical reactions: fever, dizziness, shivering, fatigue, sweating, myalgia, arthralgia, pruritus, rash, headache.
These reactions usually disappear within one or two days without treatment.
Reactions such as shock and eclampsia, vasculitis(inflammation of the blood vessels)with transient renal involvement, neurological disorders are rarely seen. If any unmentioned discomfort appeared, please seek medical help.

【CONTRAINDICATION】
Do not use the product if your child and yourself currently have:
fever, acute diseases and cold.
acute paroxysm of any chronic disease.
an allergy to any component of Anflu, especially egg or chicken protein.
guillain-barre syndrome.

【PRECAUTIONS】
(1) Do not use in the case that there is any crack in the container, the vaccine is degenerative, or there is big mass that can not be disappeared by shaking.
(2) Administration must not be via vascular route.
(3) This product should be stored at places out of the reach by children.
(4) Shake before use.
(5) Anflu should be used cautiously for patient with hypersensitive history.
(6) Anflu should not be mixed with other vaccines in the same container.
(7) As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event following the administration of the vaccine.
(8) Application of immunosuppressors may decrease or inhibit immunization reactions. People, who is administrated globulin should vaccinated the vaccine 1 month later.
(9) Please seek medical advice if:
You have defected immune function.
Ask, the advice of your doctor or pharmacist before using any medicine.
(10) Medical advice should be followed on whether or not to get vaccination during pregnancy. Lactation is not a contraindication of this product.

【STORAGE】
Store and transport between +2℃ and +8℃, protect from light, do not freeze.

【PACKAGE】
Syringe or vial, pack of 1.

【SHELF LIFE】
12 months

【QUALITY CRITERION】
Anflu complies with the authorized requirement (YBS00242008).

【AUTHORIZED NUMBER】
Junior: Guo Yao Zhun Zi S20053055
Adult: Guo Yao Zhun Zi S20053056

【MANUFACTURING ENTERPRISE】
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