The Vaccine Chosen as Prior for Children in Beijing, Shanghai and Tianjin
Healive®
- The Most Widely Used Inactivated Hepatitis A Vaccine for Chinese Children

- The first proprietary inactivated Hepatitis A vaccine in China
- Preservative free
- Fast, effective and long-lasting immune effect
- Good safety profile proved by over ten million children's inoculations
- Pre-filled syringe and vial package

Fast, Effective and Long-Lasting Immune Effect

Pre-clinical study and post-market study have shown that:
- Healive®- antibody can be generated within 2 weeks [1]
- Healive®- the antibody seroconversion can be tested in 8 days at the earliest [2]

Hepatitis A antibody dynamic change chart after one shot of Healive® [3]

- The emergency inoculation of Healive® can effectively control the hepatitis A epidemic situation [4]

When hepatitis A epidemic breaks out, the protection rate of emergency inoculation can reach 100% [5]

<table>
<thead>
<tr>
<th>Group</th>
<th>Number of subjects</th>
<th>Hepatitis A infected cases</th>
<th>Hepatitis A infection rate/100,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccination Group</td>
<td>3365</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Control Group</td>
<td>2572</td>
<td>5</td>
<td>194.4</td>
</tr>
</tbody>
</table>
**Good Safety Profile**

- Over 20 million children and adults have been inoculated by Healive® since it was first launched into market in 2002, whose safety profile has been fully proved.

- After the severe earthquake in Sichuan in 2008, 399,000 children aged from 18 months old to 12 years old in disaster area were inoculated by Healive®, which also proved its good safety profile.[8]

- We also conducted the post-market study on Healive's safety and immunogenicity with 749 subjects, whose result shows Healive® is safe and well tolerated.[7,8]

**Adverse Reaction Rate Comparison between Healive® and Imported Control Vaccine**[9]

<table>
<thead>
<tr>
<th>Local reaction</th>
<th>Systemic reaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>1%</td>
<td>1%</td>
</tr>
<tr>
<td>5%</td>
<td>3%</td>
</tr>
<tr>
<td>the First batch</td>
<td>the First batch</td>
</tr>
<tr>
<td>the Second batch</td>
<td>the Second batch</td>
</tr>
<tr>
<td>the Third batch</td>
<td>the Third batch</td>
</tr>
<tr>
<td>Imported Control Vaccine</td>
<td>Imported Control Vaccine</td>
</tr>
</tbody>
</table>

**Inoculation Schedule of Healive®**

- Two shots with 0, 6 months inoculation schedule

- 1 shot for emergency inoculation schedule. According to the study data, the antibody seroconversion rate can reach 96% after one shot vaccination.[8]

**Long - Lasting Effectiveness and Good Stability of Healive®**

- Shelf Life: 3.5 years

- Store at 37°C for 32 days, all statistics comply with the quality specification

**Specifications and Packaged Forms of Healive®**

- 2 packaged forms:
  - Pre-filled syringe - convenient for use
  - Vial - small in size and economical

- 2 specifications:
  - Pediatric dosage: 250u / 0.5ml / dose
  - Adult Dosage: 500u / 0.5ml / dose

**Suitable Population**

- Children over one year old

- Group Living Adolescents, students and military, etc.

- Travelers

- Close contact with Hepatitis A patient

- Healthcare staff

- Chronic hepatopath

- People who want to be protected from Hepatitis A vaccine


Inactivated Hepatitis A Vaccine - Healive® Introduction

[Composition and description]
Inactivated hepatitis A vaccine is cultured in human embryo lung diploid cell, followed by hampered purification, inactivation by formaldehyde and aluminum adjuvant. The vaccine is injectable suspension with trace opalescent sediment, which containing inactivated hepatitis A virus antigens, aluminum hydroxide, sodium dihydrogen phosphate, sodium chloride, and water for injection. No preservative in the product.

[Object of inoculation]
People who are at risk of hepatitis A infection.

[Therapeutic indication]
The vaccine can reduce body to generate immune reaction 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 500u of HAV antigen for adult use. 0.5ml/dose/syringe (vial) containing 250u 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., 2, 6 months of schedule). Dosage: 500u/1.0ml is recommended for adults and adolescents age 16 and above; 250u/0.5ml is recommended for children age between 1 and 15.

[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 nodules, and systemic adverse reactions including headache, fever, nausea, most of which can be self-healed 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 matters that can not be dispersed by shaking.
(3) The vaccine should be used cautiously for patient with hypertension history or family hypertensive history.

[Quality standard]
Healive® comply with the authorized requirement (WS/A - G - 029 - 2006).

[Storage and shelf – life]
Store or transport between +2°C and +8°C, protect from light, do not freeze. Shelf - Life is 42 months.

[Authorized number]
Adult: Duo Yao Zhu 2; S20000035
Junior: Duo Yao Zhu 2; S20000099