Summary of Product Characteristics

1. Name of the medicinal product:

Healive, suspension for injection in a pre-filled syringe or in a vial.
Hepatitis A Vaccine (Human Diploid Cell), Inactivated

2. Qualitative and quantitative composition

Each 0.5 ml dose for pediatric use contains:
Inactivated HAV antigen (TZ84 strain) [1], [2].....250 u [3]

[1] produced in human diploid (2BS) cells

[2] adsorbed on aluminium hydroxide

[3] In the absence of an international standardised reference, the antigen content is expressed using an in-house reference

Excipient(s):

Excipients with known effects:
Sodium chloride

For a full list of excipients, see section 6.1.

3. Pharmaceutical form

Suspension for injection in a pre-filled syringe or in a vial.
Hepatitis A Vaccine (Human Diploid Cell), Inactivated is a slightly milky-white suspension.

4. Clinical particulars

4.1 Therapeutic indications

Healive 0.5 ml dose is indicated for active immunization against infection caused by hepatitis A virus in susceptible children over 1 but below 16 years old.

The use of Healive should be based on official recommendations.

4.2 Posology and method of administration

Recommended dosage and schedule are presented as below:

Age Group	Dosage	Number of Doses	Injection Route
>1 but < 16 years old	0.5 ml	2 (6-month interval)	i.m.

In order to provide long-term protection, a second dose (booster) of a Hepatitis A Vaccine (Human Diploid Cell), Inactivated should be given. The second dose is
preferably given 612 months after the first dose. Method of

Administration

Healive should be administered by intramuscular injection in the deltoid region.

4.3 Contraindications

Subjects with known allergic reaction to any component of the vaccine, including excipients, formaldehyde and gentamycin sulfate.

4.4 Special warnings and precautions for use

Vaccination shall be postponed to subjects with acute diseases, severe chronic diseases, and chronic diseases at acute attack stage or fever.

This vaccine shall be administered with caution to the subjects with family or individual history of convulsion and to those with chronic diseases, history of
epilepsy, allergic diathesis, as well as to those with severe anaphylactic reaction following a previous injection of this vaccine.

Healive should be given with caution to individuals on anticoagulant therapy. Do not use the vaccine if the container shows abnormalities, such as crack, illegible label, exceeding expiry date or turbidity.

The vaccine shall be administered immediately after the container is opened.
Appropriate medical treatments, such as Adrenaline, should be readily available for immediate use in case of rare severe anaphylactic reaction following
vaccination. The recipients shall be observed for at least 30 minutes on site after injection.

It is possible that subjects may be in the incubation period of a hepatitis A
infection at the time of immunization. It is not known whether Healive will prevent hepatitis A in such cases.
Shake well before use.

4.5 Interaction with other medicinal products and other forms of interaction

Preliminary results suggest that the concomitant administration of a wide variety of other vaccines is unlikely to interfere with the immune response to Healive. This vaccine can be administered simultaneously with vaccines against diphtheria, tetanus, pertussis (DTP), polio (oral and inactivated), *Haemophilus influenzae* type b (Hib), measles, mumps, rubella, typhoid (oral and intramuscular), hepatitis B, cholera, Japanese encephalitis, rabies and yellow fever, without biologically

significant interference in the immunogenicity, reactogenicity or safety of the individual vaccines. (WHO position paper, June 2012)

When concurrent administration of other vaccines or IG is required, they should be administered at different sites with different syringes and needles.
No interaction with other medicinal products is currently known.

4.6 Pregnancy and Lactation

Pregnancy
Animal reproduction studies have not been conducted with Healive. It is not known whether Healive can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. However, as with all inactivated viral vaccine, the risks to the foetus are considered to be negligible. Healive should be given to a pregnant woman only if clearly needed after consult a doctor.

Lactation
It is not known whether Healive is excreted in human milk. Because many drugs excreted in human milk, caution should be exercised when Healive is administered to woman at breast feeding.

4.7 Effects on ability to drive and use machines

There are no clinical or scientific data for effects on ability to drive and use machine.

4.8 Undesirable effects

- The safety profile presented below is based on data from clinical trials, plus reactions observed through post-marketing surveillance. Moreover, the frequency of reactions from the post-marketing data was not possible to calculate.
- The most frequently reported reaction is fever, while the next most frequently reported one is pain at site of injection.
- Frequencies per dose are defined as follows:
- Very common: ≥ 10%

Common:	≥ 1% and < 10%
Uncommon:	≥ 0.1% and < 1%
Rare:	≥ 0.01% and < 0.1%
Very rare:	< 0.01%
Not Known:	Cannot be estimated from the available data

- Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

System Organ Classes	Frequency	Adverse Reaction
Application site disorders	Uncommon	Injection site reaction, such as redness and swelling, pain at the injection site
Body as a whole-general disorders	Common	Fever
	Uncommon	Fatigue
Hearing and vestibular disorders	Rare	Ear pain
Immune system disorders	Rare	Anaphylaxis
Nervous system disorders	Uncommon	Headache
Gastrointestinal disorders	Uncommon	Vomiting, nausea, abdominal pain
	Rare	Diarrhea
Respiratory system disorders	Uncommon	Coughing
Skin and appendages disorders	Rare	Rash
General disorders	Uncommon	Sore throat
	Rare	Crying

- All the above data were calculated based on company-sponsored studies.
- Post-marketing surveillance
- These adverse reactions were identified through post-marketing surveillance but were not observed in randomized controlled clinical trials.

System Organ Classes	Adverse Reaction
Application site disorders	Induration at the injection site
Psychiatric disorders	Agitation
Nervous system disorders	Convulsions, Tetany, somnolence
Respiratory system disorders	Upper respiratory tract infection
Skin and appendages disorders	Pruritus Urticaria Urticaria acute Erythema induratum Angioedema
Vascular (extracardiac) disorders	Purpura allergic

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Pharmacy and Poisons Board Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose

Few cases of overdose have been reported with Healive during the post-marketing surveillance. Adverse reactions reported following overdose were similar to those reported with normal vaccination.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Viral vaccine, ATC code: J07BC02.
Healive confers immunity against hepatitis A virus by inducing antibody titres greater than those obtained after passive immunization with immunoglobulin. Antibody appears shortly after the first injection, and 14 days after vaccination 56.7%-93% of immunocompetent subjects are seroprotected (titre above 20 mIU/ml). One month after the first dose, 69.4%95.5% of subjects have antibody titres above 20 mIU/ml.

The efficacy of Healive was evaluated in different community outbreaks. These studies indicated that administration of a single dose of Healive contributed to the termination of the outbreaks. In one study, the peak of the HAV outbreak began to decrease in 2 weeks after the primary injection. In another study, the protective efficacy was 100% in students who received vaccination.
In order to ensure long-term protection, a booster dose should be given between 6 and 12 months after the primary dose. In clinical trials, virtually all vaccinees were seropositive one month after the booster dose.

The long-term persistence of protective antibody levels to hepatitis A virus after a second dose (booster) of Healive has not been fully evaluated. Nevertheless, serological data show continuing protection against hepatitis A for up to 5 years in subjects who administrated after the full immunization.

5.2 Pharmacokinetic properties

Not applicable to a vaccine for prophylaxis.

5.3 Preclinical safety data

A long-term toxicity study has been conducted for Healive in mice and rats. No toxicity was observed in the mentioned study.

6. Pharmaceutical Particulars

6.1 List of Excipients

- Aluminum (as aluminum hydroxide)
- Disodium hydrogen phosphate
- Sodium chloride
- Sodium dihydrogen phosphate
- Water for injection

6.2 Incompatibilities
In the absence of compatibility studies, this vaccine must not be mixed with other medicinal products.

6.3 Shelf-Life
42 months.

6.4 Special Precautions for storage
Store and ship at 2-8℃, protected from light. Do not freeze.

6.5 Nature and Content of container
0.5 mL suspension in a pre-filled syringe (neutral glass Type I) with plunger-stopper (chlorobutyl), staked needle and needle shield (polystyrene) in pack size of 1.
Packs of 200 syringes per carton.
0.5 ml suspension in a vial (neutral borosilicate glass) with stopper (halogenated butyl rubber) and cap (aluminium-plastics) in pack size of 1.

Packs of 400 vials per carton.

Not all pack sizes and presentations may be marketed.

6.6 Special precautions for disposal and other handling
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorization Holder

Marketing Authorisation Holder:
Sinovac Biotech Co., Ltd.
No.39, Shangdi Xi Road, Haidian District, Beijing-100085, P.R. China

Manufacturer:
Sinovac Biotech Co., Ltd.
Workshop No. 15, Zhi Tong Road, Changping Science Park, Changping District, Beijing-102200, P.R. China

8. Marketing Authorization Number

H2024/CTD11681/24957

9. Date of first authorization/renewal of the authorization

6th May 2024

10. Date of revision of the text

12th May 2025