Final Artwork	
Item Name	Insert & PIL Healive for PFS Box
Item Code	-
Rev. No.	02
CC No.	CC-EBI-OT-020-22
Change type	1. Change “Keep between +2°C and +8°C” to “Store temperature between 2°C - 8°C” 2. Change “Simpan pada suhu +2°C and +8°C” to “Simpan pada suhu 2°C - 8°C” 3. Combine PIL & Insert in one sheet of paper
Effective Date	

Notes

Size : 210 x 160 mm
Material : 60 g offset paper (print 2-sided)
Color : K M100Y100 SINOVAC Pantone 2035C K100
Fonts :
INFORMASI PASIEN : Arial Regular 6pt
Healive® : Arial Bold 7pt
Hepatitis A Vaccine (Human Diploid Cell), Inactivated : Arial Bold 5.6pt
Others : Arial 4.5pt, 5.5pt, 6pt

INFORMASI PASIEN

Healive®

Hepatitis A Vaccine (Human Diploid Cell), Inactivated
Suspension for Injection

Baca seluruh keterangan pada Informasi Pasien ini dengan cermat sebelum Anda menerima vaksin ini karena mengandung informasi penting untuk Anda.
- Simpan Informasi Pasien ini. Anda mungkin perlu membacanya lagi.
- Jika Anda memiliki pertanyaan lebih lanjut, tanyakan kepada dokter, perawat, atau apoteker Anda.
- Vaksin ini telah diresepkan untuk Anda. Jangan menyebarkannya kepada orang lain. Itu bisa membahayakan mereka.
- Jika Anda mendapat efek samping, bicarakan dengan dokter, perawat, atau apoteker Anda. Ini termasuk apa saja kemungkinan efek samping yang tidak tercantum dalam Informasi Pasien ini.

Apa saja yang terdapat dalam Informasi Pasien ini:

1. Apa itu Healive® dan digunakan untuk apa

Healive® diindikasikan untuk imunisasi aktif terhadap infeksi yang disebabkan oleh virus hepatitis A. Dosis 1,0 mL pada orang dewasa dan remaja yang rentan berusia 16 tahun ke atas, dan dosis 0,5 mL pada anak di atas 1 tetapi di bawah 16 tahun.
Penggunaan Healive® harus berdasarkan rekomendasi resmi.

Bagaimana Healive® bekerja
- Virus tidak hidup sehingga vaksin ini tidak dapat menyebabkan infeksi hepatitis A.
- Ketika Anda diberikan vaksin Healive®, tubuh Anda akan membuat antibodi (sistem pertahanan alami tubuh) terhadap virus hepatitis A.
- Setelah 2 hingga 4 minggu, antibodi ini akan diproduksi dan akan melindungi Anda dari infeksi hepatitis A.
- Untuk memastikan perlindungan jangka panjang, Anda harus menerima vaksinasi (penguat) kedua 6 hingga 12 bulan setelah dosis pertama.
- Memiliki vaksin ini hanya akan melindungi dari hepatitis A dan tidak terhadap virus hepatitis jenis lain atau penyakit lain apa pun yang dapat menyebabkan hepatitis (radang hati).

2. Apa yang perlu Anda ketahui sebelum menerima Healive®

Healive® seharusnya tidak diberikan apabila :
- Pasien dengan reaksi alergi yang diketahui terhadap komponen vaksin apa pun, termasuk zat tambahan, formaldehida, dan gentamisin sulfat.

Peringatan dan Tindakan Pencegahan Khusus
- Vaksinasi harus ditunda untuk pasien dengan penyakit akut, penyakit kronis berat, dan penyakit kronis pada tahap serangan akut atau demam.
- Healive® harus diberikan dengan hati-hati kepada individu yang menggunakan terapi antikoagulan.
- Jangan menggunakan vaksin jika kemasan menunjukkan kelainan, seperti retak, label tidak terbaca, melebihi tanggal kedaluwarsa atau kekeruhan.
- Vaksin harus diberikan segera setelah kemasan dibuka.
- Perawatan medis yang tepat, seperti Adrenalin, harus tersedia untuk segera digunakan jika terjadi reaksi anafilaksis berat yang jarang terjadi setelah vaksinasi. Penerima harus diamati selama setidaknya 30 menit di lokasi setelah injeksi.
- Ada kemungkinan bahwa pasien mungkin dalam masa inkubasi infeksi hepatitis A pada saat imunisasi. Tidak diketahui apakah Healive® akan mencegah hepatitis A dalam kasus tersebut.
- Kocok sebelum digunakan.

Interaksi dengan Produk Obat Lain dan Bentuk Interaksi Lainnya
Beri tahu dokter atau perawat Anda jika Anda sedang minum obat apa saja. Vaksin lain dapat diberikan bersamaan dengan Healive®. Vaksin ini akan diberikan di tempat suntikan yang berbeda.

Kehamilan dan Laktasi
- Bicaralah dengan dokter atau perawat Anda jika Anda hamil atau kemungkinan sedang hamil.
- Bicaralah dengan dokter atau perawat Anda jika Anda menyusui.

Efek pada Kemampuan Mengemudi dan Menggunakan Mesin
Healive® seharusnya tidak memengaruhi kemampuan Anda untuk mengemudi atau mengoperasikan mesin. Namun, beberapa efek yang disebutkan dalam Bagian 4 "Kemungkinan efek samping" mungkin sementara mempengaruhi kemampuan mengemudi atau menggunakan mesin.

3. Bagaimana Healive® diberikan

Healive® harus diberikan dengan injeksi intramuskular di daerah deltoid.

4. Kemungkinan efek samping

Gangguan situs aplikasi
Jarang: Reaksi di tempat injeksi, seperti kemerahan dan bengkak, Nyeri di tempat suntikan
Tubuh sebagai gangguan umum
Umum: Demam
Jarang: Kelelahan
Gangguan pendengaran dan vestibular:
Jarang: sakit telinga
Gangguan sistem kekebalan tubuh:
Jarang: Anafilaksis
Gangguan sistem saraf:
Jarang: Sakit kepala
Gangguan pencernaan:
Jarang: Muntah, Mual, Nyeri perut
Jarang: Diare
Gangguan sistem pernapasan:
Jarang: Batuk
Gangguan kulit dan pelengkap:
Langka: Ruam
Gangguan umum:
Jarang: Sakit tenggorokan
Langka: Menangis

5. Bagaimana cara menyimpan Healive®

- Jauhkan dari pandangan dan jangkauan anak-anak
- Simpan pada suhu 2°C - 8°C dalam lemari pendingin
- Terlindung dari cahaya
- Jangan disimpan dalam lemari pembeku
- Jangan gunakan setelah tanggal kedaluwarsa yang tercantum pada label dan karton.
- Jangan membuang obat apa pun melalui air limbah atau limbah rumah tangga. Tanyakan apoteker Anda cara membuang obat yang tidak lagi Anda gunakan. Langkah-langkah ini akan membantu melindungi lingkungan.

6. Isi di dalam kemasan dan informasi lainnya

Healive® memiliki 4 kemasan, yaitu :
(1) Dus, 1 prefilled-syringe @ 0.5 mL : Reg. No.: DKI2257300243A1
(2) Dus, 1 vial @ 0.5 mL : Reg. No.: DKI2257300243A2
(3) Dus, 1 prefilled-syringe @ 1.0 mL : Reg. No.: DKI2257300243B1
(4) Dus, 1 vial @ 1.0 mL : Reg. No.: DKI2257300243B2

HARUS DENGAN RESEP DOKTER

Diproduksi Oleh:
SINOVAC BIOTECH CO., LTD.
No.15, Zhi Tong Road, Changping Science Park, Changping District, Beijing

Diimpor Oleh:
PT Etana Biotechnologies Indonesia
Jakarta, Indonesia

SINOVAC

160 mm

210 mm

front page

DISETUJUI OLEH BPOM: 29/02/24

ID EREG100007VR12400026;
EREG100007VR12400012

Healive®

HEPATITIS A VACCINE (HUMAN DIPLOID CELL), INACTIVATED

【INSTRUCTION】

Intramuscular Injection

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

Quality and Quantitative Composition

Each 1,0 mL dose for adult use contains:
Inactivated HAV antigen (TZ84 strain) [1, 2] ……..…..…….. 500 u [3]
Each 0,5 mL dose for junior use contains:
Inactivated HAV antigen (TZ84 strain) [1, 2] ……..…….. 250 u [3]
[1] produced in human diploid (2BS) cells
[2] adsorbed on aluminum hydroxide
[3] In the absence of an international standardized reference, the antigen content is expressed using an in-house reference
Excipients: aluminum (as aluminum hydroxide), sodium dihydrogen phosphate, disodium hydrogen phosphate, sodium chloride and water for injection.
No preservative is used in Healive®.

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.

Therapeutic Indication

Healive® 1,0 mL dose is indicated for active immunization against infection caused by hepatitis A virus in susceptible adults and adolescents of 16 years of age and above, and 0.5 mL dose in children over 1 but below 16 years old.
The use of Healive® should be based on official recommendations.

Posology and Method of Administration

Posology
Recommended dosage and schedule are presented as below:

Age Group	Dosage	Number of Doses	Injection Route
≥ 16 years old	500 u / 1,0 mL	2 (6 months interval)	i.m.
>1 but < 16 years old	250 u / 0,5 mL	2 (6 months 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 6-12 months after the first dose.
Method of Administration
Healive® should be administered by intramuscular injection in the deltoid region.

Contraindications

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

Special Warning 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.
- 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 immunisation. It is not known whether Healive® will prevent hepatitis A in such cases.
- Shake well before use.

Interaction with Other Medicinal Products and Other Forms of Interactions

No studies of Healive® on interaction with other medicinal products have been conducted. It is not know whether Healive® can use interaction with other medicinal products.

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.

Effects on Ability to Drive and Use Machine

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

Undesirable Effects

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%

Clinical trial data

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

Post-marketing surveillance

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, Anigoedema
Vascular (extracardiac) disorders:
Purpura allergic

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.

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.
The efficacy of Healive® was evaluated in different community outbreaks. These studies indicated that administration of a single dose of Healive® contributed to termination of the outbreaks. In one study, the peak of 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.

Pharmacokinetic Properties

Not applicable to vaccine for prophylaxis.

Preclinical Safety Data

Long-term toxicity study has been conducted for Healive® on mice and rats. No toxicity was observed in mentioned studies.

Immunogenicity Data

The seroconversion rate and geometric mean concentration (GMC) of antibody were used to evaluate the immunogenicity of Healive®. Seroconversion was defined by a concentration of less than 20 mIU/ml any injections with a concentration of 20 mIU/ml or more after any injections. Antibody concentration was detected with ELISA, microparticle enzyme immunoassay and electrochemiluminescence method.

Table 1 Seroconversion Rate and GMC of Antibody 1 month after Full-Vaccination

Age Group	Study	Immunogenicity Results of 1 Month after Full Vaccination (0,6 month)			
		N	No. of positive cases (Seroconversion rate %)	GMC (mIU/ml)	95%CI (mIU/ml)
1-15 years	HAVS012	287	287(100%)	3436,8	(3047,3,3876,0)
	HAVS017	66	66(100%)	8905,5	(7566,5,10482)
	BR-HAV-CT-301	52	52(100%)	9248,79	-
	HAVS004	33	33(100%)	5963	(6300,5642)
	HAVS007	10	10(100%)	4301	(1509,12260)
	HAVS011	33	33(100%)	5963	(8233,4318)
16-59 years	HAVS016	69	69(100%)	4812,71	(4011,22,5774,36)
	HAVS002	53	53(100%)	1657	(1317,2084)
	BR-HAV-CT-302	121	121(100%)	4832,24	-
	HAVS020	138	138(100%)	59,58	(58,7,60,4)

Incompatibilities

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

Shelf Life

42 months.

Nature and Contents of Container

1,0 mL or 0.5 mL suspension in 1 pre-filled syringe or vial.

Marketing Authorization Numbers

0.5 mL PFS dose for junior use : Reg. No.: DKI2257300243A1
0.5 mL VIAL dose for junior use : Reg. No.: DKI2257300243A2
1,0 mL PFS dose for adult use : Reg. No.: DKI2257300243B1
1,0 mL VIAL dose for adult use : Reg. No.: DKI2257300243B2

The vaccine satisfies the recommendations given by the World Health Organization in WHO TRS No. 858, Annex 2, 1995 and Pharmacopoeia of the people's Republic of China (Edition 2010).

HARUS DENGAN RESEP DOKTER

Store temperature between 2°C - 8°C
Protect from light. Do not freeze.

Manufactured by:
SINOVAC BIOTECH CO., LTD.
Add.: No.15, Zhing Tong Road, Changping Science Park, Changping District, Beijing. Postal code: 100085.
Website: www.sinovac.com

Imported by:
PT Etana Biotechnologies Indonesia
Jakarta - Indonesia

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