SUMMARY OF PRODUCT CHARACTERISTICS/BROCHURE

A. Name of Medicine

Vecon Adult – Recombinant Hepatitis B Vaccine (*Saccharomyces cerevisiae*)

B. Dosage Form

Suspension for Injection

1.0 ml/dose/syringe

C. Drug Description

Vecon Adult – Recombinant Hepatitis B Vaccine (*Saccharomyces cerevisiae*) is a preparation made of purified hepatitis B surface antigen (HBsAg) expressed by the recombinant *Saccharomyces cerevisiae*. After purification of HBsAg, a quantity of aluminum adjuvant is added to make the vaccine. The vaccine is a milky-white suspension with stratified precipitate which can be dispersed by shaking. It contains no preservative.

D. Drug Composition

Components of formulation (per 1.0 mL of final bulk①)

Components of formula	Content	Function
Hepatitis B Surface Antigen	20 μg	Active ingredient
Sodium chloride	9.0 mg	Solvent
Potassium aluminum sulfate dodecahydrate②	3.04 mg	Adjuvant
Sodium Hydroxide②	0.77 mg	Adjuvant

Note: ① Calculated as 1.0 mL of final bulk, due to the final product strength of 1.0ml/prefilled syringe.

② Potassium aluminum sulfate and sodium hydroxide are added to form Kombinasi Aluminum Hydroxide Adjuvant

E. Indications

Vecon adult can induce immunity against hepatitis B virus in recipients following immunization. It is used to prevent hepatitis B. Eligible for the subject susceptible to hepatitis B virus, 16 years of age and above.

F. Posology and Method of Administration

The immunization schedules for Hepatitis B vaccine should be based on official recommendations.

Vecon Adult should be injected intramuscularly. The deltoid muscle is the preferred site for intramuscular injection for adults.

For individuals aged 16 years and above who are susceptible to the Hepatitis B virus, three injection (1.0 mL each dose) for a complete immunization course at the schedule of 0, 1, and 6 months will be given.

G. Direction for use

The vaccine should be shaken well to obtain a homogeneous white suspension prior to expelling air from the syringe, and should be inspected visually for any particulate matter and/or variation of physical aspect prior to administration. Do not use if there is foreign matter in the content. The vaccine shall be administered immediately after the container is opened.

H. Contraindications

(1) Subjects with known allergic reaction to any component of the vaccine, including excipients and formaldehyde.
(2) Subjects with acute diseases, severe chronic diseases, chronic diseases at acute attack stage or fever.
(3) Subjects with allergic history of Hepatitis A &B combined vaccine or Hepatitis B vaccine.
(4) Subjects with uncontrolled epilepsy or other progressive diseases of nervous system.

I. Warnings and Precautions

Precautions

(1) Adrenaline should be available for first aid in case of severe anaphylactic reactions. The recipients shall be observed for at least 30 minutes on site following injection.
(2) The vaccine shall be administered with caution to the subjects with family or individual history of convulsion and those with chronic diseases, history of epilepsy or allergic diathesis.
(3) Normally the subjects who had abnormal reactions such as high fever or convulsions after first vaccination should not be vaccinated for the second time. The newborns to Hepatitis B Surface Antigen and/or HBeAg-positive mothers shall follow the doctor's instructions as for whether to receive the second and third injections.
(4) Shake the vaccine container well before use. Do not use the vaccine if the container shows abnormalities, such as crack, illegible label, exceeding expiry date or turbidity.

(5) The vaccine shall be administered immediately after the container is opened.

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

J. Drug Interactions

Concomitant administration with other vaccines: No clinical research has been conducted to study the impact of synchronized immunization (immunization of other vaccines prior to or following the immunization of this vaccine, or immunization of this vaccine in combination with other vaccines) on the immunogenicity of this vaccine. No data are available to be used for assessing the effects of simultaneous vaccination of this vaccine and any other vaccine.

Concomitant administration with immunosuppressive drugs. There are no clinical studies of concomitant administration with immunosuppressant drugs. However, the use of immunosuppressants typically lowers the immune response to the vaccination.

K. Fertility, Pregnancy and Breastfeeding

Pregnancy

There are no data from the use of Recombinant Hepatitis B vaccine (Saccharomyces cerevisiae) in pregnant women. Therefore, the use of this vaccine should be avoided during pregnancy.

Breast-feeding

It is unknown whether Recombinant Hepatitis B vaccine (Saccharomyces cerevisiae) is excreted in human milk.

Fertility

Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. (see sections **Preclinical Safety Data**)

L. Effects on Ability to Drive and Use Machines

HepB vaccine has no or negligible influence on the ability to drive and use machines.

Howerver, some of the adverse effects may temporarily affect the ability to drive or use machines.

M. Side effects

Summary of safety profile

The safety profile presented below is based on a Phase III clinical study, Phase IV clinical study, PSUR (May 2015-2020), and PSUR (May 2020 – 2022). Phase III clinical study conducted in

Danyang City, Jiangsu China with 1092 subjects receiving at least one dose of this vaccine. Phase IV clinical study conducted in Ganyu District and Funing County of Lianyungang City with the number of subjects receiving this vaccine is 5046 subjects.

The most commonly reported adverse reactions were pain, fever, nausea and vomiting, diarrhea, myalgia, induration, swelling, erythema, pruritus, and weariness. These adverse reactions were usually mild or moderate in intensity and resolved within a few days after vaccination.

Most other adverse reactions were uncommon and similarly reported between the study groups.

Summary table of side effects reactions

Tabulated list of adverse reactions

Adverse reactions are listed below by MedDRA system organ class and frequency:

Very common : (≥ 1/10)
Common : (≥ 1/100 to < 1/10)
Uncommon : (≥ 1/1,000 < 1/100)
Rare : (≥ 1/10,000 < 1/1,000)
Very rare : (< 1/10,000)

Adverse Reaction

System Organ Class	Frequency	Adverse Reactions
Immune system disorder	Uncommon	Allergic reaction, rash
	Rare	Anaphylaxis shock
Gastrointestinal disorder	Common	Nausea and vomiting, diarrhea
Respiratory system disorder	Uncommon	Cough
Nervous system disorder	Uncommon	Headache
Musculoskeletal and connective tissue disorder	Common	Myalgia
General disorders and administration site conditions	Very common	Pain, fever
	Common	Induration, swelling, erythema, pruritus, weariness
	Rare	Aseptic abscess

Adverse events should be reported to Bio Farma via call center Bio Care 1500810 and Pusat Farmakovigilans/MESO Nasional Direktorat Pengawasan Keamanan, Mutu, dan Ekspor Impor Obat, Psikotropika, Prekursor dan Zat Aktif Badan Obat dan Makanan
Jl. Percetakan Negara No. 23, Jakarta Pusat, 10560
Email: pv-center@pom.go.id
Phone: +62-21-4244691 Ext. 1079

Website: https://e-meso.pom.go.id

N. Overdose and Treatment (if applicable)

Overdose with this product is unlikely due to its presentation as a pre-filled syringe.

O. Drug Mechanisms, and/or Pharmacodynamic and/or Pharmacokinetics

Pharmacodynamic properties

Pharmacotherapeutic group: vaccines, Hepatitis vaccines, hepatitis B, purified antigen; ATC code: J07BC01.

This HepB vaccine is prepared from purified Hepatitis B Surface Antigen expressed by the yeast Saccharomyces cerevisiae, which is subjected to fed-batch culture after the S gene carrying Hepatitis B Surface Antigen and vectors constructed by regulatory units related to S gene expression are transferred into it (the yeast Saccharomyces cerevisiae). The active ingredient is Hepatitis B Surface Antigen, which can stimulate the body to produce specific immunity.

Clinical trial

In Phase III clinical trials in healthy subjects (16 years old and above), immunogenicity of 1.0ml/dose containing 20μg of Hepatitis B Surface Antigen antigen, was evaluated and compared with the HepB vaccines manufactured by GlaxoSmithKline. Collecting venous blood and separating serum before the first injection and 7 months after the first injection. The effective serum is those with pre-vaccination and post-vaccination serum. ChemiLuminescence method was used for quantitative detection of anti-HBs. The summary of immunogenicity result of this product is shown as below.

Anti-HBs positive conversion rate: there was no significant difference between the test group (98.22%) and the 20 ug control group (97.64%). The test group (98.22%) is higher than 10 ug control group (89.96%), and the difference was significant.

Anti-HBs level after vaccination: the test group (GMC 1770.81 mIU/ml) is better than that of 20 ug control group (GMC 952. 13 mIu/ml). The 20 ug control group is better than that of the 10 ug control group (GMC 496.74 mIu/ml), and the difference was significant.

Phase IV study

In the phase IV clinical trial study, a total of 5046 subjects were enrolled in this study. Among them, 800 subjects were observed for immunogenicity. Before immunization and on one month after the whole-course immunization, 5 mL of peripheral venous blood samples were collected from the immunogenicity group, and serum was separated. Anti-HBs were quantitatively assayed by chemiluminescence method. Observation indicators included positive conversion rate of anti-HBs and geometric mean concentration (GMC) of anti-HBs.

After subjects received 3 doses of 20 μg/1.0 mL hepatitis B vaccine in the trial period, the positive conversion rate of anti-HBs in the test group was 98.11%, and the geometric mean concentration (GMC) of anti-HBs was 778.7 ± 5.6 mIU/mL; the positive conversion rate of anti-HBs in the control group was 92.54%, and the GMC of anti-HBs was 296.3 ± 5.1 mIU/mL

It was suggested that 3 doses of 20 μg/1.0 mL hepatitis B vaccine achieved a good immune effect in healthy population aged 16 years and above.

Pharmacokinetic properties

Not applicable.

P. Non-Clinical Safety Data

Single dose toxicity evaluation was performed by intramuscular injection of HepB into mice. Repeated dose toxicity evaluation was performed by intramuscular injection of HepB into cynomolgus monkeys. During the test in single and repeated dose toxicity studies, there were no reported deaths of test animals, abnormalities in clinical signs, laboratory examinations, gross pathology or hispathology. The NOAEL (No Observed Adverse Effect Level) of the test vaccine in mice was 600 micrograms/kilogram and 30 μg/kg in cynomolgus monkeys.

Q. Incompatibilities (if the product need to be reconstituted before use)

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

R. Storage

Store and ship at 2-8°C, protect from light. Freezing is strictly forbidden.

During storage, a white deposit and clear supernatant can be observed. This does not constitute a sign of deterioration.

The shelf life of the vaccine is 36 months.

S. Packaging Type and Size

Box, 1 Pre-Filled Syringe (PFS) @ 20 µg/1.0 mL (1 dose)

Nature and contents of container:

1.0 ml suspension for injection in pre-filled syringe (Neutral borosilicate glass) with a plunger stopper (Chlorinated butyl rubber plunger) and protective-tip cap (Polyisoprene Rubber).

T. Other Listed Dosage Form and Packaging (if any)

Box, 1 Pre-Filled Syringe (PFS) @ 10 µg/0.5 mL (1 dose)

Box, 1 vial@ 10 µg/0.5 mL (1 dose)

U. Marketing Authorization Number

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V. Drug Class

Prescription Drug

W. Special Warning

On Medical Prescription Only

- Do not use if there is foreign matter in the content.
- The vaccine shall be administered immediately after the container is opened.
- No special requirements for disposal.
- Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Manufactured by.

Shenzhen Kangtai Biological Products Co., Ltd.

No. 18, Shutianpu Road, Matian Street, Guangming District, Shenzhen

Zip Code: 518106

Hotline: 4008806992

Tel: 86-755-26988686

Fax: 860755026988585

Website: www.biokangtai.com

Imported by.

PT Bio Farma (Persero)

Jl. Pasteur No. 28 – Bandung 40161 - Indonesia

PO Box 1136. Tel. +62 22 2033755

Fax. +62 22 2041306

www.biofarma.co.id

INFORMASI PRODUK UNTUK PASIEN

Vecon Adult ® Vaksin Hepatitis B Rekombinan **Suspensi Injeksi**

Informasi Produk (PIL) ini mengandung informasi yang dapat membantu untuk mengetahui manfaat dan risiko penggunaan Vecon Adult® yang sudah atau akan Anda terima. Bicarakan kepada tenaga kesehatan yang merawat Anda apabila ada pertanyaan lebih lanjut.

Apa itu Vecon Adult®?
Vecon Adult® merupakan produk suspensi injeksi yang mengandung vaksin Hepatitis B rekombinan. Vaksin ini dapat merangsang tubuh untuk menghasilkan kekebalan dan digunakan untuk mencegah penyakit menular yang disebabkan oleh virus hepatitis B.

Terbuat dari apakah Vecon Adult®?
Vecon Adult® terbuat dari pemurnian *Hepatitis B Surface Antigen* yang diekspresikan oleh *Saccharomyces cerevisiae* rekombinan. Setelah dilakukan pemurnian, dilakukan penambahan eksipien dan dijerap dengan ajuvan aluminium. Vecon Adult® tidak mengandung bahan pengawet.

Seperti apa bentuk Vecon Adult®?
Vecon Adult® ini berupa suspensi berwarna putih susu dengan endapan bertingkat yang dapat didispersikan dengan cara dikocok. Vecon Adult® tersedia dalam dosis tunggal *prefilled syringe*.

Apa yang terkandung dalam Vecon Adult®?
Dalam setiap 1.0mL Vecon® terdapat 20µg *Hepatitis B Surface Antigen* dengan zat tambahan Natrium klorida 9,0mg, Alumunium kalium sulfat dodekahidrat 3,04mg dan Natirum hidroksida 0,77mg.

Untuk apa Vecon Adult® digunakan?
Digunakan sebagai imunisasi aktif untuk mencegah terjadinya infeksi yang disebabkan oleh virus Hepatitis B pada individu berusia 16 tahun ke atas.

Bagaimana cara pemberian Vecon Adult®?
Individu berusia 16 tahun ke atas yang rentan terhadap virus hepatitis B akan menerima tiga suntikan (1,0mL tiap dosis) vaksin primer pada jadwal 0, 1 dan 6 bulan melalui otot lengan atas.

Siapa yang tidak boleh divaksinasi dengan Vecon Adult®?

- Individu yang memiliki riwayat alergi terhadap komponen vaksin, termasuk eksipien dan formaldehida.
- Individu yang memiliki riwayat penyakit akut, penyakit kronis berat, penyakit kronis eksaserbasi akut, atau demam.
- Individu dengan riwayat alergi terhadap vaksin kombinasi Hepatitis A & B atau vaksin Hepatitis B.
- Individu yang memiliki riwayat epilepsi tidak terkontrol atau penyakit progresif lainnya pada sistem saraf.
- Wanita hamil.

Laporkan ke dokter atau tenaga kesehatan jika Anda memiliki salah satu dari kondisi di atas.

Apa yang perlu diperhatikan saat menggunakan Vecon Adult®?
Bicarakan dengan dokter atau tenaga Kesehatan Anda sebelum vaksinasi jika:

- Memiliki riwayat atau keluarga dengan riwayat kejang, dan/atau memiliki penyakit kronis, riwayat epilepsi, atau kecenderungan alergi.
- Mengalami reaksi abnormal seperti demam tinggi atau kejang setelah vaksinasi pertama.
- Sedang hamil.
- Sedang menyusui.

Obat dan makanan apa yang harus dihindari jika mendapatkan Vecon Adult®?
Belum terdapat informasi terkait obat atau makanan yang harus dihindari ketika mendapatkan Vecon Adult®.
Pemberian bersamaan dengan obat imunosupresif, termasuk imunosupresan, obat kemoterapi, agen alkilasi, obat sitotoksik, dan kortikosteroid dapat mengurangi respons imun tubuh terhadap vaksin Hepatitis B. Laporkan ke dokter atau tenaga kesehatan jika Anda sedang menjalani pengobatan sebelum mendapatkan Vecon Adult®.

Apakah Vecon Adult® boleh digunakan pada wanita hamil dan menyusui?
Belum terdapat informasi terkait pemberian Vecon Adult® pada wanita hamil dan menyusui. Tidak ada data apakah virus dari Vecon Adult® disekresikan dalam air susu ibu (ASI). Penggunan vaksin ini pada ibu hamil harus dihindari. Diskusikan kepada dokter Anda jika ingin mendapatkan vaksin ini dalam kondisi hamil atau menyusui.

Dapatkah saya mengemudi atau mengoperasikan mesin setelah mendapatkan Vecon Adult®?
Vecon Adult® tidak berpengaruh terhadap kemampuan mengemudi dan mengoperasikan mesin. Namun, beberapa efek samping dapat memengaruhi kemampuan mengemudi atau menggunakan mesin untuk sementara.

Apa efek samping yang mungkin terjadi setelah pemberian Vecon Adult®?
Berdasarkan laporan uji klinis, efek samping yang mungkin terjadi dapat berupa reaksi lokal dan reaksi sistemik. Reaksi lokal yang umum dilaporkan berupa nyeri, demam, mual dan muntah, diare, mialgia, indurasi, bengkak, eritema, pruritus, dan kelelahan. Gejala-gejala ini dilaporkan bersifat ringan hingga sedang. Umumnya, tidak diperlukan pengobatan khusus dan gejala dapat hilang secara spontan. Jika diperlukan, pengobatan simtomatik dapat diberikan.
Efek samping yang jarang terjadi dapat berupa benjolan bernanah, dan syok anafilaksis. Syok anafilaksis dapat terjadi dalam satu jam setelah vaksinasi. Tindakan darurat termasuk suntikan adrenalin harus segera diberikan.

Jika terjadi efek samping lain selain yang tertera diatas, segera hubungi dokter atau tenaga kesehatan. Masyarakat dapat melaporkan efek samping ke Bio Farma melalui call center Bio Care : 1500810.

Seperti apa tanda/gejala kelebihan dosis dalam pemberian Vecon®?
Kelebihan dosis pada pemberian produk ini tidak mungkin terjadi karena produk berupa jarum suntik yang sudah berisi 1 dosis vaksin.

Bagaimana cara penyimpanan Vecon Adult®?
Vecon Adult® disimpan pada suhu 2-8°C dan terlindung dari cahaya. Vaksin ini tidak boleh dibekukan. Selama penyimpanan, endapan putih dan cairan bening dapat terlihat. Ini bukan merupakan tanda kerusakan. Dokter atau tenaga kesehatan akan mengocok dengan baik untuk memperoleh suspensi putih yang homogen sebelum mengeluarkan udara dari jarum suntik, dan memeriksa secara visual untuk setiap partikel dan/atau perubahan aspek fisik sebelum pemberian. Dokter atau tenaga kesehatan tidak

akan menggunakan vaksin jika ada benda asing di dalam isinya, atau sudah melewati tanggal kadaluwarsa yang tertera pada dus dan label.

Berapa lama Vecon Adult® dapat digunakan setelah kemasan dibuka?
Vecon Adult® harus segera diberikan setelah kemasan dibuka.

Kemasan:
Suspensi injeksi
Vecon Adult® : Dus, 1 Pre-Filled Syringe (PFS) @ 20 µg/1,0 mL (1 dosis)

No. Reg:

Diproduksi oleh: Shenzhen Kangtai Biological Products Co., Ltd
No.18, Shutianpu Road, Matian Street, Guangming District, Shenzhen, China

Diimpor oleh: PT Bio Farma (Persero)
Jl. Pasteur No. 28 – Bandung 40161 - Indonesia

Harus Dengan Resep Dokter