

AUSTRALIA

Manufacturer: **CSL LIMITED**  
45 Poplar Road  
Parkville, Victoria 3052

Telephone: 9 389 1272  
Fax: 9 389 1887  
Telex: 'SERUMS' MELBOURNE

Type of vaccine: Hepatitis B Immunoglobulin Liquid

Proprietary name: Hepatitis B Immunoglobulin (Human)

Available packaging: 100 units, 400 units

Delivery time:

Recommended storage temperature: 2 - 8 degrees C

Shelf life: 1 year

Stability:

Other remarks:

Vaccine exportation: No

Production capacity: Sufficient for local requirements

Stability at 8 ° C: Adequate for above shelf life

Stability at 37 ° C: No data

BELGIUM

Manufacturer: **SMITHKLINE BEECHAM PHARMACEUTICALS**  
89 rue de l'Institut  
B-1330 Rixensart

Telephone: 32 2 656 8754  
Fax: 32 2 656 9034  
Telex: 63251 SB BIO B

Type of vaccine: Hepatitis B vaccine (rDNA) - aqueous suspension;  
for I.M. administration

Proprietary name: ENGERIX™ B

Available packaging: 1 dose, 25 x 1 dose, 100 x 1 dose; 10 dose vials

Delivery time: 4 weeks for monodose; 6-8 weeks for 10 dose vials  
depending on quantities

Recommended storage  
temperature: 2-8 deg C

Shelf life: 3 years

Stability: 36 months at 2-8 deg C, 1 month at 37 deg. C; 7 days  
at 45 Deg C

Other remarks: Vaccine has 2 dosage recommendations: 1) Adults  
& Children 10 years and older, 20 µg/ml 2)  
Children under 10 years, 10 µg/dose -Freezing  
must be avoided

Vaccine exportation: Yes

Production capacity:

Stability at 8 ° C: 3 years

Stability at 37 ° C: 1 month

BELGIUM

Manufacturer: **SMITHKLINE BEECHAM PHARMACEUTICALS**  
89 rue de l'Institut  
B-1330 Rixensart

Telephone: 32 2 656 8754  
Fax: 32 2 656 9034  
Telex: 63251 SB BIO B

Type of vaccine: Hepatitis A vaccine(inactivated)-aqueous suspension; for I.M. administration

Proprietary name: HAVRIX (Registered)

Available packaging: 1 dose vial x 1

Delivery time: 4 weeks

Recommended storage temperature: 2-8 deg C

Shelf life: 2 years or 3 years, according to the country

Stability: 3 years at 2-8 deg C, 3 weeks at 37 deg. C

Other remarks: Freezing must be avoided

Vaccine exportation: Yes

Production capacity:

Stability at 8 ° C: 3 years

Stability at 37 ° C: 3 weeks

CROATIA

Manufacturer: **INSTITUTE OF IMMUNOLOGY**  
Rockefellerova 2  
41000 Zagreb

Telephone: 385 1 430 333  
Fax: 385 1 277 278  
Telex: 21864 VACC HR

Type of vaccine: Human hepatitis B Immunoglobulin

Proprietary name: ZAHUHEBIG

Available packaging: 1 box/1 vial/250 I.U.; 1 box/1 vial/500 I.U.

Delivery time: 2 months

Recommended storage temperature: 2 - 8 degrees C

Shelf life: 3 years

Stability: Stable under recommended storage conditions

Other remarks: Satisfies WHO requirements

Vaccine exportation: Yes

Production capacity: 10 l

Stability at 8 ° C: in revaluation

Stability at 37 ° C: in revaluation

CUBA

**Manufacturer:** **CENTRE FOR GENETIC ENGINEERING AND BIOTECHNOLOGY (CIGB)**  
Ave 31 between 158 y 190, Cubanacan, Playa, PO Box 6162  
Havana

Telephone: 53 7 218 164  
Fax: 53 7 218070  
Telex: ING GEN CU 512330

Type of vaccine: Hepatitis B recombinant vaccine

Proprietary name: Hepatitis B recombinant vaccine

Available packaging: the following packed in a single box and then in a box of 10 units: 1 vial of 10 mg; 1 vial of 20 mg; 1 vial of 100 mg The following packed in a 25 units box and then in a box of 6x25 units; 1 vial of 10 mg; 1 vial of 20 mg; 1 vial of 30 mg

Delivery time: According to requested conditions

Recommended storage temperature: 2 - 8 degrees C

Shelf life: 3 years

Stability: Stable during 3 years when stored at 4±2°C

Other remarks:

Vaccine exportation: Yes

Production capacity: 35-40 million doses of 20 mcg / year

Stability at 8 ° C: 3 years

Stability at 37 ° C: At least 1 week

CUBA

Manufacturer: **CENTRO NATIONAL DE BIOPREPARADOS**  
Biocen  
Habana

Telephone:

Fax:

Telex:

Type of vaccine: Hepatitis B Vaccine made by recombinant DNA techniques

Proprietary name:

Available packaging:

Delivery time:

Recommended storage temperature:

Shelf life:

Stability:

Other remarks:

Vaccine exportation:

Production capacity:

Stability at 8 ° C:

Stability at 37 ° C:

CUBA

Manufacturer: **LABIOFAM**

Telephone:

Fax:

Telex:

Type of vaccine: Moquillo y Hepatitis (bivalent)

Proprietary name: Vacunas Bivalente contra el moquillo y la Hepatitis canimo

Available packaging: Frascos de 1 dosis

Delivery time: 30 días

Recommended storage temperature: 4-8 deg C

Shelf life: 1 año

Stability: 1 año a 4-8 deg C

Other remarks: Vacuna Viva liofilizada contra la hepatitis y el moquillo canino, elaborada en cultivos celulares

Vaccine exportation: No

Production capacity: 50 000 Frascos

Stability at 8 ° C:

Stability at 37 ° C:

FRANCE

Manufacturer: **PASTEUR -MERIEUX VACCINS & SERA**  
17 rue Bourgelat  
69002 Lyon

Telephone: 47 41 79 22

Fax: 206 464 F

Telex:

Type of vaccine: Purified adjuvanted hepatitis B vaccine, prepared exclusively from plasmas of asymptomatic carriers of HBsAg

Proprietary name: HEVAC B PASTEUR Hepatitis B vaccine

Available packaging: Pack of 1 unidose, ready to use disposable syringe containing 1 ml of vaccine

Delivery time:

Recommended storage temperature: 2 - 8 degrees C

Shelf life: 3 years

Stability:

Other remarks: Indication: prevention of viral hepatitis B in all persons at risk of infection

Vaccine exportation:

Production capacity:

Stability at 8 ° C:

Stability at 37 ° C:

GERMANY

Manufacturer: **BEHRINGWERKE AKTIENGESELLSCHAFT**  
Postfach 1140  
D-3550 Marburg (Lahn) 1

Telephone: (06421) 39-0  
Fax: 48 23 200  
Telex: MARBURGLAHN Fax: (064021) 31388

Type of vaccine: Human Hepatitis B Immunoglobulin for i.m.  
administration Liquid

Proprietary name: Hepatitis B Immunoglobulin Behring

Available packaging: Ampoules; 1 ml = 200 I.U.; 5 ml = 1000 I.U.

Delivery time: Depending on countries and quantities: 4-8 weeks

Recommended storage temperature: 2 - 8 degrees C

Shelf life: Maximum 36 months

Stability: Stable under recommended storage conditions

Other remarks: 1 ml contains: 100-170 human immunoglobulin,  
with 200 I.U. HBsAg antibodies

Vaccine exportation:

Production capacity:

Stability at 8 ° C:

Stability at 37 ° C:

JAPAN

**Manufacturer:** DENKA SEIKEN CO., LTD  
Taiyo bldg., 12-1 Kabuto-chu, Nihonbashi, Chuo-ku  
Tokyo 103

Telephone: 03 3669 9091  
Fax: 03 3664 1005  
Telex:

**Type of vaccine:** Hepatitis A Vaccine, freeze dried

**Proprietary name:** Freeze dried Hepatitis A vaccine "SEIKEN"

**Available packaging:** 1 dose/vial/package, solvent 0.7 ml/vial (water for injection)

**Delivery time:** 8 months

**Recommended storage temperature:** <10 deg C, but avoid freezing

**Shelf life:** 3 years

**Stability:** Good

**Other remarks:**

**Vaccine exportation:** No

**Production capacity:** 150 000 doses/year

**Stability at 8 ° C:** 39 months

**Stability at 37 ° C:** at least 6 months

JAPAN

Manufacturer: **mitsubishi chemical corporation**  
2-2-24 Higashi-Shinagawa, Shinagawa-Ku  
Tokyo 140

Telephone: 03 5463 0718  
Fax: 03 5463 0704  
Telex:

Type of vaccine: Recombinant Precipitated Hepatitis B Vaccine  
(CHO-derived)

Proprietary name: R-HB VACCINE "MITSUBISHI"

Available packaging: 5µg/0.25ml/vial x 10; 10µg/0.05ml/vial X 10

Delivery time: 150 days when bulk material in store, depends on  
quantities

Recommended storage  
temperature: 10 deg C or lower, avoid freezing

Shelf life: 2 years

Stability: 27 months(at 12±1°C)

Other remarks: Manufacturing Facility: Specialty Products Center,  
Kashima Plant, Mitsubishi Chemical Corporation

Vaccine exportation: Not up to now

Production capacity: 21 lot/year(30,000 vials/lot)

Stability at 8 ° C: 2 years

Stability at 37 ° C: no data

JAPAN

Manufacturer: **THE CHEMO-SERO-THERAPEUTIC RESEARCH  
INST. General Manager of Human Vaccine  
Department  
668 Okubo, Shimizu  
Kumamoto 860**

Telephone: 81 96 345 6500  
Fax: 81 96 344 9269  
Telex: KUMAMOTO KAKETSUKEN CSTI J

Type of vaccine: Recombinant adsorbed Hepatitis B Vaccine (yeast-derived)

Proprietary name: BIMMUGEN

Available packaging: 1. 10 µg/0.5 ml/vial for adult use 2. 5 µg/0.25 ml/vial for pediatric use

Delivery time: 6 months

Recommended storage temperature: 10 degrees C or lower away from light, avoid freezing

Shelf life: 2 years following day of state validation

Stability: 27 months at 27 degrees C; 3 months at 40 degrees C

Other remarks:

Vaccine exportation: Yes

Production capacity: 600 000 doses/year

Stability at 8 ° C: not performed

Stability at 37 ° C: 3 months

JAPAN

Manufacturer: **THE CHEMO-SERO-THERAPEUTIC RESEARCH  
INST. General Manager of Human Vaccine  
Department**  
668 Okubo, Shimizu  
Kumamoto 860

Telephone: 81 96 345 6500  
Fax: 81 96 344 9269  
Telex: KUMAMOTO KAKETSUKEN CSTI J

Type of vaccine: Freeze-dried Inactivated Tissue Culture Hepatitis A  
vaccine

Proprietary name: AIMMUGEN

Available packaging: 1 dose / vial; 1x vial of diluent

Delivery time: 180 days when bulk materials in store, depends on  
quantities

Recommended storage  
temperature: 10 degrees C or lower away from light, avoid  
freezing of diluent to prevent breakage of the vial.

Shelf life: 3 years from the following day of state validation

Stability: 39 months at 10 degrees C; 6 months at 40 degrees  
C

Other remarks:

Vaccine exportation: No

Production capacity: 200 000 doses / year

Stability at 8 ° C: not performed

Stability at 37 ° C: not performed

JAPAN

**Manufacturer:** **THE GREEN CROSS CORPORATION**  
1-3-3 Imabashi, Chuo-ku  
Osaka 541

Telephone: 06 227 4607  
Fax: 06 226 1767  
Telex: J63467 BPCJ

**Type of vaccine:** Recombinant Precipitated Hepatitis B Vaccine  
(Yeast derived)

**Proprietary name:** HBY

**Available packaging:** 10 µg/vial and 5 µg/vial

**Delivery time:** 6 months

**Recommended storage temperature:** 2-8 deg C

**Shelf life:** 3 years

**Stability:** An adequate stability at 2-8 deg C over a 39-month period for both strengths; also confirmed to be stable at 11±1 °C for 39 months and at ambient temperature (11-39°C) for 27 months

**Other remarks:**

**Vaccine exportation:** No

**Production capacity:** 300000 vials (as 10µg size)/year

**Stability at 8 ° C:** exact data not available (Please see "stability")

**Stability at 37 ° C:** exact data not available (Please see "stability")

JAPAN

**Manufacturer:** THE RESEARCH FOUNDATION FOR  
MICROBIAL DISEASES OF OSAKA UNIVERSITY  
3-1 Yamada-Oka, Suita  
Osaka

Telephone: 06 (877) 5121  
Fax: 06 876 1984  
Telex: BIKEN-ZAIDAN SUITA JAPAN

Type of vaccine: Hepatitis B Virus Vaccine

Proprietary name: BIKEN-HB (Recombinant Hepatitis B Vaccine)

Available packaging: 0.5 ml/vial x 10

Delivery time: depends on quantities

Recommended storage temperature: 10 degrees C or lower, avoid freezing

Shelf life: 1 year

Stability: Stable at 10°C for 30 months

Other remarks:

Vaccine exportation: No

Production capacity: Not less than 600,000 doses/year

Stability at 8 ° C: no data

Stability at 37 ° C: no data

KOREA

Manufacturer: **DONG SHIN PHARMACEUTICAL CO., LTD**  
355-2 Seogyo-dong ,Mapo-ku  
Seoul

Telephone: 324-7111-5

Fax: VITAPHA K27579

Telex: VITAPHARM SEOUL

Type of vaccine: r-DNA Hepatitis B Vaccine

Proprietary name: Engerix - B

Available packaging: Vials of 0.5 ml; 1 ml; 10 ml; box of 20 vials of 10 ml

Delivery time:

Recommended storage temperature: 2 - 8 degrees C

Shelf life: 26 months

Stability: Stable under recommended storage conditions

Other remarks:

Vaccine exportation:

Production capacity:

Stability at 8 ° C:

Stability at 37 ° C:

SWITZERLAND

Manufacturer: **SWISS SERUM AND VACCINE INSTITUTE  
BERNE**  
P.O. Box 2707  
CH-3001 Berne

Telephone: 41 31 980 6 111  
Fax: 41 31 980 6 775  
Telex: 912 618

Type of vaccine: Virosomal vaccine against hepatitis A

Proprietary name: Epaxal Berna

Available packaging: Syringe of 0.5 ml; 10x1 syringe of 0.5 ml; Ampoule  
of 0.5 ml

Delivery time: A few days to several weeks

Recommended storage  
temperature: 2 - 8 degrees C

Shelf life: 1 year

Stability: Stable under recommended storage conditions

Other remarks:

Vaccine exportation: Yes

Production capacity: upon demand

Stability at 8 ° C: 1 year

Stability at 37 ° C: 1 day

SWITZERLAND

**Manufacturer:** **SWISS SERUM AND VACCINE INSTITUTE**  
**BERNE**  
P.O. Box 2707  
CH-3001 Berne

Telephone: 41 31 980 6 111  
Fax: 41 31 980 6 775  
Telex: 912 618

**Type of vaccine:** Human immunoglobulin with high hepatitis A antibody titre

**Proprietary name:** Globuman Berna Hepatitis A

**Available packaging:** vial of 2 ml = 200 I.U.; Vial of 5 ml = 500 I.U.;  
Syringe of 2 ml = 200 I.U.

**Delivery time:** A few days to several weeks

**Recommended storage temperature:** 2 - 8 degrees C

**Shelf life:** 3 years

**Stability:** Stable under recommended storage conditions

**Other remarks:**

**Vaccine exportation:** Yes

**Production capacity:** upon demand

**Stability at 8 ° C:** 3 years

**Stability at 37 ° C:** 2 months

SWITZERLAND

Manufacturer: **SWISS SERUM AND VACCINE INSTITUTE  
BERNE  
P.O. Box 2707  
CH-3001 Berne**

Telephone: 41 31 980 6 111

Fax: 41 31 980 6 775

Telex: 912 618

Type of vaccine: Hepatitis B Vaccine, yeast derived

Proprietary name: Heprecomb Berna

Available packaging: Syringe of 0.5 ml (10 mcg); Syringe of 0.5 (5 mcg);  
Ampoule of 0.5 ml (10 mcg)

Delivery time: A few days to several weeks

Recommended storage temperature: 2 - 8 degrees C

Shelf life: 2 years

Stability: Stable under recommended storage conditions

Other remarks:

Vaccine exportation: Yes

Production capacity: upon demand

Stability at 8 ° C: 2 years

Stability at 37 ° C: 1 day

SWITZERLAND

Manufacturer: **SWISS SERUM AND VACCINE INSTITUTE  
BERNE  
P.O. Box 2707  
CH-3001 Berne**

Telephone: 41 31 980 6 111  
Fax: 41 31 980 6 775  
Telex: 912 618

Type of vaccine: Human hepatitis B immunoglobulin

Proprietary name: Hepuman Berna

Available packaging: Vial of 0.5 ml=100 I.U.; Vial of 1 ml = 200 I.U.; Vial  
of 2 ml = 400 I.U.; Vial of 5 ml = 1000 I.U.

Delivery time: A few days to several weeks

Recommended storage  
temperature: 2 - 8 degrees C

Shelf life: 4 years

Stability: Stable under recommended storage conditions

Other remarks:

Vaccine exportation: Yes

Production capacity: upon demand

Stability at 8 ° C: 4 years

Stability at 37 ° C: 2 months

UNITED STATES OF AMERICA

Manufacturer: **BAYER; Pharmaceutical Division**  
800 Dwight Way  
Berkeley, CA 94710

Telephone: 510-705-5000  
Fax: 510-705-5553  
Telex:

Type of vaccine: Hepatitis B Immuno Globulin (human)

Proprietary name: HyperHep(trademark) Hepatitis B Immune Globulin (Human)

Available packaging: .5 ml neonatal single dose syringes; 1 ml and 5 ml multiple dose vials

Delivery time: n/a

Recommended storage temperature: 2 - 8 degrees C (36-46°F)

Shelf life: 3 years when stored at 2-8°C

Stability: Meets requirements for 3-year shelf life

Other remarks: Product is licensed in U.S. and many other countries

Vaccine exportation: Yes

Production capacity: n/a

Stability at 8 ° C: Meets requirements for 3-year shelf life

Stability at 37 ° C: n/a

