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Recommendations for Hepatitis B Vaccination in Adults

Updated 2026 (Erratum 20.10.2026)

The CSMI recommends hepatitis B vaccination for people considered to be at risk.

However, the CSMI encourages vaccination for all other people who wish to protect themselves against HBV.

➢ Serological testing after vaccination:

Routine measurement of anti-HBs antibodies following vaccination (full vaccination course) is not recommended for healthy children and adults, except for at-risk groups.

➢ Recommended vaccination schedule based on immune status and risk of infection:

- **Immunocompetent individuals:**

  Type of vaccine: standard vaccine (Engerix B 20, HBVaxPro10)

  Standard schedule: M0, M1, M6 or accelerated schedule: D0, D7, D21, M12.

- **Special case: immunocompetent healthcare workers:**

  Anti-HBs antibody titre test 4–8 weeks after the final dose

  - **If the level is < 10 mIU/ml**: a second course of vaccination should be offered in the absence of infection, with an anti-HBs antibody test carried out 1 to 2 months after this second course.
  - **If the anti-HBs level is < 10 mIU/ml despite two complete vaccination courses and no signs of current or past infection**: permanent non-responders; administration of specific hepatitis B immunoglobulin (HBIG) if exposed to HBV.

- **Special case: patients with chronic renal failure undergoing haemodialysis:**

  Type of vaccine: high-dose vaccine (40 mcg) or adjuvanted

  Schedule: M0, M1,M2 and M6 for adjuvanted vaccine;

  M0, M1 and M6 for high-dose vaccine 40 mcg.

  Check the vaccine response after the primary vaccination course; arrange for serological monitoring and booster doses depending on the risk of exposure to infection.

Epidemiology and aim of vaccination

Worldwide, an estimated 2.5 billion people are currently infected or have been infected with the hepatitis B virus (HBV), according to the latest WHO report, representing one-third of the global population; 254 million people have chronic hepatitis B. In 2022, 1.2 million new infections were reported worldwide. With over one million deaths per year, hepatitis B was the second leading cause of death from infectious disease after COVID-19 in 2022; 43,000 deaths per year were reported in Europe in 2022.

The highest prevalence is in sub-Saharan Africa (>8%) and the Western Pacific (>5%).

Transmission of HBV is virtually non-existent in Luxembourg, with only a few cases reported each year.

The number of hepatitis B virus infections reported to the authorities in Luxembourg by laboratories was 344 cases in 2025 and 415 cases in 2024; however, the reporting system does not allow for a distinction to be made between newly acquired and chronic infections.

Vaccination is the most effective way to prevent hepatitis B. According to the WHO, 190 countries worldwide have introduced hepatitis B vaccination into their childhood immunisation schedules, with an excellent safety, immunogenicity and efficacy profile. Hepatitis B vaccination results in protection rates of almost 100 per cent in healthy children and almost 95 per cent in healthy adults.

The persistence of anti-HBs antibodies is linked to the peak antibody level reached following primary vaccination: the higher the initial titre, the more likely the antibodies are to persist above the threshold of 10 mIU/mL. However, a decrease or disappearance of circulating antibodies does not necessarily mean a loss of protection, as vaccination induces an immune memory specific to HBsAg. This can result, even several decades after the primary vaccination, in a rapid and robust anamnestic (memory) response following a booster dose.

Following natural exposure to the hepatitis B virus, this immune memory is likely to enable a rapid immune response and control of the infection before the onset of chronic infection or clinical hepatitis. However, human data allowing this anamnestic response to be characterised directly following natural exposure remain limited, as most studies demonstrating immune memory use a vaccine dose as a booster (‘challenge’) antigen.

Long-term follow-up studies have shown that immune memory and protection against clinical forms of the infection persist for several decades following full vaccination. Data are available up to 35–40 years after primary vaccination, but the exact duration of protection has not been definitively established and cannot be equated with the constant persistence of anti-HBs antibodies.

In Europe, a recent study published in **The Lancet Regional Health – Europe** highlights a stagnation, or even a decline, in vaccination coverage with three doses in 18 of the 27 EU countries

between 2019 and 2024. The third dose is, however, part of the primary vaccination schedule required to complete the recommended vaccination course.

In Luxembourg, the Higher Health Council recommended the vaccination of infants and adolescents in May 1994, and it was included in the Ministry of Health's official immunisation schedule as early as 1996. In the meantime, the babies who were vaccinated have grown into adults, and the vaccination programme for adolescents aged 12 to 18 was discontinued in 2008.

The aims of vaccination are twofold:

- individual protection;
- herd immunity; only by protecting the entire population will the virus cease to be transmitted, thereby enabling the elimination of chronic HBV infections. Ultimately, the infection and the disease can be eradicated.

Transmission, disease progression and complications.

Humans are the only reservoir for HBV.

The virus is transmitted sexually, through percutaneous contact with infected blood, or via mother-to-child transmission.

Acute hepatitis – which occurs between 60 and 150 days after infection – can be fulminant in 0.1–0.6 per cent of cases, with a mortality rate of 70 per cent.

The development of chronic infection is inversely related to the age at which the infection was contracted. It is observed in 80–90 per cent of perinatal infections and in fewer than 5 per cent of infections occurring in otherwise healthy adults. Co-infection with the human immunodeficiency virus (HIV) or the hepatitis delta virus, and alcohol consumption, exacerbate liver damage. Without treatment, the disease will progress to cirrhosis, hepatocellular carcinoma and liver failure.

Vaccines

Several vaccines are available, with the first vaccine having been marketed in 1982. The combined vaccines used in infants are not included in the list below.

Vaccine	Composition	Marketing Authorisation
ENGERIX B 20®	20 µg of recombinant hepatitis B virus surface antigen (HBsAg), adsorbed onto hydrated aluminium hydroxide	**2000**
Heplisav-B®	20 µg of recombinant HBsAg + 3,000 µg of **CpG 1018** (cytidine-phosphoguanosine) adjuvant	**2021**
HBVAXPRO®	10 µg of AgHBs adsorbed onto amorphous aluminium hydroxyphosphate sulphate	**2001**
HBVAXPRO 40®	40 µg of AgHBs adsorbed onto amorphous aluminium hydroxyphosphate sulphate	**2001**
FENDRIX®	20 µg of recombinant HBsAg + 50 µg of **MPL** adjuvant (3-O-deacyl-4'-monophosphoryl lipid A) + 0.5 mg of aluminium phosphate	**2005**
TWINRIX®	20 µg of HBsAg + 720 units of inactivated hepatitis A virus antigen	**1996**

ENGERIX B 20®

The vaccine contains 20 µg of HBsAg, produced by Saccharomyces cerevisiae cells which, following genetic recombination, contain the gene encoding HBsAg. It is combined with 0.5 mg/ml of aluminium hydroxide and a phosphate-buffered saline solution.

It is administered intramuscularly into the deltoid muscle in people aged 15 years and over.

The schedule consists of 3 doses at M0, M1 and M6.

An accelerated schedule may be followed with administration at on days 0, 7 and 21, and a booster dose after one year (M12).

When used in patients with renal impairment on haemodialysis or in people living with HIV, a four-dose (double-dose) schedule is recommended, with 40 µg per dose at M0, M1, M2 and M6.

It may be administered during pregnancy and whilst breastfeeding.

It may be administered simultaneously with other vaccines, injected at a different site.

Adverse effects are as follows:

Frequency	Adverse reactions
Common	Pain, redness or hardening at the injection site
Rare	*General:* fatigue, malaise, fever, flu-like symptoms Neurological: dizziness, headache, paraesthesia *Gastrointestinal*: diarrhoea, nausea, vomiting, abdominal pain Musculoskeletal: myalgia, arthralgia *Skin*: rash, itching, hives
Very rare	*General*: anaphylaxis, serum sickness, lymphadenopathy *Cardiovascular*: syncope, hypotension *Neurological*: paralysis, neuropathy, Guillain-Barré syndrome, optic neuritis, multiple sclerosis, encephalitis, encephalopathy, meningitis, convulsions Haematological: thrombocytopenia *Musculoskeletal*: arthritis *Respiratory*: bronchospasm *Skin*: angioedema, erythema multiforme

FENDRIX

It consists of 20 µg of recombinant AgHBs, 50 µg of MPL adjuvant (3-0-desacyl-4'-monophosphoryllipid A) and 0.5 mg of aluminium phosphate. One dose is 0.5 ml.

It is specifically recommended for people with end-stage renal failure who are either on pre-dialysis or on dialysis.

It is administered intramuscularly according to a regimen comprising four doses: M0, M1, M2 and M6.

There are no data regarding use during pregnancy and breast-feeding.

Reported adverse effects:

Frequency	Adverse effects
Very common	*General disorders and administration site conditions:* swelling at the injection site, fatigue, pain, redness
Common	*Nervous system disorders*: headache *Gastrointestinal disorders*: gastrointestinal disturbances
Uncommon	*General*: fever or other reactions at the injection site
Rare	*General*: Chills, hot flushes, thirst, asthenia *Ear and labyrinth disorders*: vertigo *Musculoskeletal disorders*: tendinitis, back pain *Infections and infestations*: viral infection *Immune system disorders*: allergy *Psychiatric disorders*: nervousness

HBVAXPRO 10

It consists of recombinant HBV surface antigen (HBsAg) 10 micrograms absorbed onto aluminium hydroxyphosphate sulphate (0.50 milligrams), produced in the yeast Saccharomyces cerevisiae using recombinant DNA technology. This vaccine may contain traces of formaldehyde and potassium thiocyanate, which are used in the manufacturing process. The dose is 1 ml.

It is administered intramuscularly into the deltoid muscle in people over 15 years of age. It may be administered subcutaneously in cases of coagulation disorders.

It is administered intramuscularly according to a 3-dose schedule at M0, M1 and M6, or a 4-dose schedule at M0, M1, M2 and M12.

It must not be administered in the event of an allergic reaction following a previous administration or in the event of an allergy to formaldehyde or potassium thiocyanate.

It must not be administered in the event of a febrile illness or acute infection.

There are no data on use during pregnancy and breastfeeding. It may be administered simultaneously with other vaccines injected at a different site.

Reported adverse reactions:

Frequency	**Adverse reactions**
Common	Pain, redness or hardening at the injection site.
Rare	*General:* fatigue, malaise, fever, flu-like symptoms *Neurological*: dizziness, headache, paraesthesia *Gastrointestinal*: diarrhoea, nausea, vomiting, abdominal pain *Musculoskeletal*: myalgia, arthralgia, polyarteritis nodosa *Skin*: rash, pruritus, urticaria, alopecia, eczema
Very rare	*General*: anaphylaxis, serum sickness, lymphadenopathy *Cardiovascular*: syncope, hypotension *Neurological*: paralysis, neuropathy, Guillain-Barré syndrome, optic neuritis, multiple sclerosis, encephalitis, encephalopathy, meningitis, convulsions *Haematological*: thrombocytopenia *Musculoskeletal*: arthritis *Respiratory*: bronchospasm *Skin*: angioedema, erythema multiforme

HBVAXPRO 40

It consists of the recombinant surface antigen of the hepatitis B virus (40 µg), produced in Saccharomyces cerevisiae (strain 2150-2-3) using recombinant DNA technology, adsorbed onto amorphous aluminium hydroxyphosphate sulphate (0.50 mg Al+)

It is indicated for the vaccination of people aged 15 and over with end-stage renal disease who are either pre-dialysis or on dialysis.

The vaccination schedule consists of 3 doses at M0, M1 and M6.

It is administered intramuscularly, preferably into the deltoid muscle.

In exceptional cases, this vaccine may be administered subcutaneously to patients with thrombocytopenia or haemorrhagic disorders.

Caution should be exercised when administering the vaccine to pregnant or breastfeeding women.

It may be administered in combination with other vaccines using separate injection sites.

It may be used to complete a primary vaccination course or as a booster in individuals who have previously received another hepatitis B vaccine.

Reported adverse reactions:

Frequency	**Adverse reactions**
Common	*General*: local reactions (at the injection site): transient pain, erythema, induration.
Very rare	*General*: fatigue, fever, malaise, flu-like symptoms. *Haematological and immune system*: thrombocytopenia, lymphadenopathy, serum sickness, anaphylaxis, periarteritis nodosa. *Nervous system*: paraesthesia, paralysis, peripheral neuropathies, neuritis, myelitis, encephalitis, demyelinating disease of the central nervous system, exacerbation of multiple sclerosis, multiple sclerosis, convulsions, headaches, dizziness, syncope. *Ocular*: uveitis. *Vascular*: hypotension, vasculitis. *Respiratory*: bronchospasm. *Gastrointestinal*: vomiting, nausea, diarrhoea, abdominal pain. *Dermatological:* rash, alopecia, pruritus, urticaria, erythema multiforme, angioedema, eczema. *Musculoskeletal*: arthralgia, arthritis, myalgia, pain in the extremities.

HEPLISAV B

It consists of 20 mcg of hepatitis B surface antigen (HBsAg) produced in yeast cells (*Hansenula polymorpha*) using recombinant DNA technology. It is combined with 3000 mcg of cytidine phosphoguanosine CpG 1018 adjuvant,

It may be indicated for people aged 18 years and over.

It is administered intramuscularly into the deltoid muscle. The vaccine must not be administered intravenously, subcutaneously or intradermally.

The schedule consists of two doses administered one month apart (M0 and M1). The need for a booster dose has not been established.

In patients with renal impairment, a 4-dose schedule is recommended at M0, M1, M2 and M4.

There are no data available for use in pregnant or breastfeeding women.

The most commonly observed adverse effects are reactions following injection. These include: pain at the injection site (41.7 per cent), fatigue (21.4 per cent), headaches (20.1 per cent), malaise (13.8 per cent) and myalgia (12.5 per cent).

The HEPLISAV B vaccine is not currently available in Luxembourg.

Further information:

Monovalent recombinant hepatitis B vaccines, such as Engerix-B® and HBVAXPRO®, are generally considered interchangeable for completing a vaccination course. However, Fendrix®, an adjuvanted vaccine indicated for patients with renal impairment, is not strictly interchangeable with these vaccines under its marketing authorisation. Nevertheless, its use as a revaccination strategy in individuals who are poor responders or non-responders to conventional vaccines is supported by several clinical studies demonstrating improved immunogenicity in these populations

Immunogenicity and efficacy

Hepatitis B vaccines are highly effective: approximately 90–95 per cent of healthy adults develop an adequate immune response following vaccination, characterised by an anti-HBs titre of ≥ 10 mIU/mL. The duration of protection is long; a booster dose is not required. A titre of less than 10 mIU/ml, measured 1 to 2 months after the initial primary vaccination course of 3 injections, is considered to indicate a lack of response to the vaccine.

However, a small percentage of people (around 5–10 per cent) do not develop a sufficiently high level of protective antibodies following vaccination. This lack of response to the hepatitis B vaccine is a significant public health concern. Several risk factors for non-response have been identified, including advanced age, male sex, obesity, smoking and excessive alcohol consumption. Genetic factors also appear to influence the immune response to the vaccine.

Several studies have highlighted differences in the immune response to the hepatitis B vaccine according to sex, with women generally exhibiting a stronger immune response than men. This observation is consistent with the broader finding that women often develop more robust immune responses following vaccination than men.

Studies have shown that antibody levels decline over time, with a negative correlation between anti-HBs antibody titres and the time elapsed since vaccination.

The main risk associated with a long interval since the last HBV vaccination is a reduction in protection against hepatitis B virus infection. This protection decreases significantly more than 20 years after vaccination, with older people and those with compromised immune systems being particularly affected.

Protection against hepatitis B may persist even after the disappearance of detectable anti-HBs antibodies in the serum, thanks to the immunological memory induced by vaccination. This

protection relies not only on memory B cells capable of rapidly producing antibodies upon re-exposure to the virus, but also, according to available data, on the involvement of memory T cells.

Anti-HBs antibody levels decline gradually over time, more frequently in people vaccinated during early childhood than in those vaccinated during adolescence. However, immune memory generally persists despite the decline in antibodies and enables a rapid response following a booster dose.

The immune response is also weaker in immunocompromised individuals, the elderly and those with renal impairment.

In studies, the new adjuvanted vaccines provide better protection than non-adjuvanted vaccines. In non-responders, the new adjuvanted vaccines also elicit a better immune response than non-adjuvanted vaccines or Twinrix.

In a study comparing Fendrix with a double dose of Engerix B 20 in 165 patients with kidney disease requiring dialysis, 91 per cent versus 84 per cent had protective antibodies, and the duration of protection was longer: 80 per cent versus 51 per cent at 3 years with the Fendrix vaccine compared with a double dose of Engerix B 20.

The trials assessed the rates of seroprotection ([1] , TSP) following the second dose of HEPLISAV B, compared with the rates following the third dose of HepB-alum (such as Engerix B). The TSP and the peak geometric mean concentration (GMC) following a 2-dose regimen of HEPLISAV B were statistically superior to those following a 3-dose regimen of HepB-alum.

[1] percentage of vaccinated individuals whose anti-HBs antibody levels were ≥ 10 mIU/mL following vaccination

Management of at-risk individuals who do not respond to hepatitis B vaccination: an international comparison

Country	Reference threshold	Follow-up after primary vaccination	Management in the event of an inadequate response	Following failure of several doses
France	No response: <10 IU/L	4–8 weeks	Several additional doses, up to 3 (maximum 6 doses in total)	Serological monitoring and assessment after each additional dose until a level of > 10 IU/L is reached
United States	No response: <10 mIU/mL	1–2 months	1 additional dose, then, if the level remains < 10 IU/L, two further doses (second full course)	Permanent non-responder after 6 doses; HBIG in the event of high-risk exposure
United Kingdom	No response: <10 mIU/mL	1–2 months	Second full course (3 doses)	Persistent non-responder after 6 doses; specific management, in particular HBIG following exposure
Switzerland	≥100 IU/L (protective level) following vaccination[2]	4–8 weeks after the 3rd dose	10–99 IU/L: additional dose and follow-up; <10 IU/L: revaccination strategy	Up to 6 doses depending on the response; post-exposure prophylaxis if necessary
Germany	≥100 IU/L (protective level) following vaccination	4–8 weeks after the 3rd dose	10–99 IU/L: additional dose followed by repeated monitoring; <10 IU/L: HBsAg/anti-HBc testing followed by full revaccination	Up to 6 doses; management following persistent failure to be discussed on a case-by-case basis

Despite their differences, all recommendations agree on one key point: a healthcare professional whose anti-HBs level remains below 10 IU/L following the recommended revaccination regimens must be considered inadequately protected against HBV and must receive specific management in the event of occupational exposure, in particular with anti-hepatitis B immunoglobulins.

[2] If the anti-HBs level is > 10 IU/l at least 5 years after the final dose (e.g. following exposure), the healthcare professional is considered to be protected.

CSMI recommendation:

➢ People at risk of hepatitis B infection

Hepatitis B vaccination is primarily recommended for:

- Sexual partners of people who are HBsAg carriers;
- People living in the same household as a person who is HBsAg-positive;
- Men who have sex with men;
- People who have multiple sexual partners;
- People who inject drugs;
- Healthcare professionals (including trainees), paramedics, law enforcement officers and anyone at risk of infection whilst carrying out activities that may involve exposure to biological agents or contaminated blood through contact with patients, the bodies of deceased persons, or biological materials;
- Residents and staff in care homes for people with disabilities;
- People with chronic kidney failure, undergoing haemodialysis, peritoneal dialysis or home dialysis;
- People who have had an organ transplant;
- People who are HIV-positive;
- People with diabetes;
- People with chronic hepatitis C or another chronic liver condition;
- Travellers – particularly those planning a long-term stay – in regions with high endemicity.

However, the CSMI encourages vaccination for all other people who wish to protect themselves against HBV.

➢ Serological testing after vaccination:

Routine testing for anti-HBs antibodies after vaccination (full vaccination course) is not recommended for healthy children and adults.

Serological testing to measure anti-HBs antibodies following vaccination is nevertheless recommended for the following individuals:

- Babies born to HBsAg-positive mothers
- People at occupational risk of exposure to HBV
- Patients on haemodialysis
- People living with HIV
- Sexual partners of people with chronic hepatitis B
- People who inject drugs and share injection equipment

The anti-HBs antibody level should ideally be checked 1 to 2 months after completion of the primary vaccination course.

➢ Proposed vaccination schedule based on immune status and risk of infection:

- **Immunocompetent individuals:**

  Type of vaccine: standard vaccine (Engerix B 20, HBVaxPro10)

  Schedule:

  - standard: M0, M1, M6;
  - accelerated: D0, D7, D21, M12.

- **Special case: immunocompetent healthcare professionals:**

Immunocompetent healthcare workers whose vaccine response (anti-HBs antibody titre >10 mIU/ml 4–8 weeks after the final dose) has been documented do not require a booster dose.

A titre of less than 10 mIU/ml measured 1 to 2 months after the primary vaccination is considered to indicate a lack of response to the vaccine.

If the titre is <10 IU/L, a second course of vaccination should be offered provided there is no infection.

- Supplement the serological testing with HBsAg and anti-HBc tests;
- a full new course of vaccination must be administered;
- anti-HBs antibody levels must be re-assessed 1 to 2 months after this second course.

The HEPLISAV-B® vaccine is not currently available in Luxembourg. Nevertheless, the results of several studies suggest that it could be an option for revaccination in individuals who show no immune response following a standard hepatitis B vaccination schedule.

Individuals who continue to have an anti-HBs titre below 10 mIU/ml despite two complete vaccination courses and who show no signs of current or past infection are considered documented non-responders. In the event of exposure to the virus, they must receive specific anti-hepatitis B immunoglobulin (HBIG) to ensure their protection.

People who have not completed their vaccination course should simply finish it, regardless of how much time has elapsed since the last dose, and then undergo the recommended serological screening.

- **Special case: patients with chronic kidney disease undergoing haemodialysis**:

Unlike immunocompetent individuals, in whom immune memory is generally sufficient to ensure long-lasting protection following an adequate initial response, patients on dialysis constitute a population in whom protection may deteriorate rapidly.

The vaccine response may be weaker or less long-lasting than in immunocompetent individuals. It is therefore recommended not only to verify the vaccine response following the primary vaccination course, but also to arrange for serological monitoring and booster doses depending on the risk of exposure to infection.

Vaccine type: high-dose vaccine (40 mcg) or adjuvanted

Schedule: M0, M1,M2 and M6 for adjuvanted vaccine;

M0, M1 and M6 for high-dose vaccine 40 mcg;

The Council reserves the right to make minor typographical corrections to this document at any time.
However, corrections affecting the meaning are automatically included in an erratum and result in a new version of the advice.

This recommendation has been adapted from the 2011 recommendation in line with the most recent data and drafted by Dr Thérèse STAUB. It was discussed and approved at the meeting on 22 September 2026 by the members of the CSMI. This recommendation is subject to review in light of developments in the epidemic, advances in knowledge, European pharmacovigilance data and real-world observational data.

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