Centers for Disease Control and Prevention

Vaccine Safety

Vaccine Safety Home

Hepatitis B Vaccines

Safety Information

About Hepatitis B

Hepatitis B is a liver infection caused by the hepatitis B virus. It is spread when infected blood, semen, or another body fluid enters the body of a person who is not infected. This can happen through sexual contact, using syringes, needles, or other drug-injection equipment previously used by an infected person, or from mother to baby at birth. The virus can spread from an infected individual even if they do not look or feel sick.

For some people, hepatitis B is an illness lasting 1 to 3 months, with symptoms that can include fever, fatigue, loss of appetite, nausea, vomiting, abdominal pain, dark urine, clay-colored bowel movements, joint pain, and jaundice (yellow color in the skin or eyes). But for others, it can become a chronic (long-term) infection that may last a lifetime and might not have symptoms for many years. Risk for chronic infection is related to age at infection: approximately 90% of infected infants become chronically infected, compared with 2%–6% of adults. Chronic hepatitis B can lead to serious health issues, like cirrhosis (scarring of the liver) or liver cancer.

Learn more about hepatitis B.

The following vaccines can protect against hepatitis B.

Vaccine Information Statements

Vaccine Information Statements (VISs) are information sheets produced by CDC that explain both the benefits and risks of a vaccine.

Hepatitis B

Hepatitis B vaccine

Available Vaccines

There are 7 licensed hepatitis B-containing vaccines currently available in the United States: 4 vaccines that protect against hepatitis B only, 1 vaccine that protects against both hepatitis A and B, and 2 childhood vaccines that protect against hepatitis B and other diseases.

Who Should Get Hepatitis B Vaccine

Hepatitis B vaccine is given as a series of 2, 3, or 4 shots, depending on the vaccine formula and health needs of the person getting vaccinated. CDC recommends hepatitis B vaccine for:

- All infants within 24 hours of birth (usually 3 doses completed over a 6-month period)

- Children and adolescents younger than 19 years of age who have not yet gotten the vaccine

Talk with your healthcare provider about vaccines.

They can answer questions and offer advice based on your specific health needs.

- People who are at increased risk of hepatitis B due to travel to certain countries, exposure to blood in the workplace, household or sexual exposure to an infected person, injection drug use or certain medical conditions
- Anyone who wants protection against hepatitis B

For more information, see Who should get vaccinated against hepatitis B.

Child and Adult Immunization Schedules
Get CDC's official recommended immunization schedules for children, adolescents, and adults.

Manufacturer Package Inserts

Vaccines against hepatitis B:

These shots contain only hepatitis B vaccine.

- **Engerix-B** [PDF – 16 Pages] : The Food and Drug Administration (FDA) approved this vaccine in 1989 for use in people from birth through adulthood, although the dose varies by age group.
- **Heplisav-B** [PDF – 11 Pages] : FDA approved this vaccine in 2017 for use in people 18 years and older.
- **PREHEVBRIO** [PDF – 12 Pages] : FDA approved this vaccine in 2021 for use in people 18 years and older.
- **Recombivax HB** [PDF – 10 Pages] : FDA approved this vaccine in 1986 for use from birth through adulthood, although the dose varies by age group.

Vaccine against hepatitis A & B:

- **Twinrix** [PDF – 15 pages] : FDA approved this combination vaccine in 2001 for use in people 18 years and older. It protects against hepatitis A and hepatitis B.

Childhood vaccines that include hepatitis B:

These shots contain hepatitis B vaccine plus other vaccines

- **Pediarix** [PDF – 24 Pages] : FDA approved this combination vaccine in 2002 for use in infants and children 6 weeks through 6 years old. It protects against hepatitis B, diphtheria, tetanus, pertussis, and polio.
- **VAXELIS** [PDF – 20 Pages]: FDA approved this combination vaccine in 2018 for use in children 6 weeks through 4 years of age. It protects against hepatitis B, diphtheria, tetanus, pertussis, and polio.

Common Side Effects

Vaccines, like any medicine, can have side effects. Many people who get a hepatitis B vaccine have no side effects at all. The most common side effects include injection site pain, soreness, or redness, headache, and fatigue, and are usually mild lasting 1-2 days.

Hepatitis B vaccines

- Pain, soreness, redness, or swelling in the arm where the shot was given
- Headache
- Fever
- Fatigue
- Irritability, diarrhea, loss of appetite in healthy infants and children who received (Recombivax, Vaxelis, Pediarix)
- Vomiting, crying, drowsiness in children (Vaxelis, Pediarix)

Who Should Not Get Hepatitis B Vaccine

Tell your vaccine provider if the person getting the vaccine:

- Has had a severe allergic reaction, such as anaphylaxis, after a previous dose or any component of the vaccine they are getting
- Has a yeast allergy
- Has had an allergic reaction to neomycin (if they are getting Twinrix)

Note: PREHEVBRIO vaccine is the only hepatitis B vaccine that **does not** contain yeast, making it safe for people who are allergic to yeast.
Note: Until safety data are available, providers should not vaccinate pregnant women needing hepatitis B vaccination with Heplisav-B.

Women who might have received Heplisav-B during pregnancy (usually before knowing they are pregnant) are encouraged to enroll in the **Heplisav-B pregnancy registry**. Contact Dynavax Technologies Corporation, phone: 1-844-443-7734.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting hepatitis B vaccine.

More information about contraindications and precautions.

More Information

Hepatitis B Questions and Answers for the Public
Learn more about the hepatitis B virus and the vaccines that provide protection.

Who Should Not Get Vaccinated
Some people should not get certain vaccines or should wait before getting them. Read the CDC guidelines for each

vaccine

Hepatitis B Vaccine – ACIP Recommendations and Guidance
Official guidance on hepatitis B vaccine from the Advisory Committee on Immunization Practices (ACIP).

Hepatitis B Questions and Answers for Health Professionals
Information for clinicians on hepatitis B virus, vaccination, and treatment.

Severe allergic reactions following vaccination are rare but can be life threatening.
Symptoms of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness.

If such reactions occur, call 9-1-1 and get the person to the nearest hospital.People should tell their healthcare provider about any allergies they have before getting any vaccine.

Report Possible Adverse Events To VAERS

The Vaccine Adverse Event Reporting System (VAERS) is an early warning system, co-managed by CDC and FDA, that monitors for potential vaccine safety problems.

Healthcare providers and vaccine manufacturers are required by law to report certain adverse events following vaccination to VAERS; patients and caregivers can also submit reports.

For more information, see Report an Adverse Event to VAERS .

A Closer Look at the Safety Data

- A Vaccine Safety Datalink (VSD) study compared deaths among newborns vaccinated with hepatitis B and unvaccinated newborns. The study found no differences between vaccinated and unvaccinated newborns.

  Source: Lack of association between hepatitis B birth immunization and neonatal death: a population based study from the Vaccine Safety Datalink project [Pediatric Infect Dis J. 2004]
- CDC reviewed Vaccine Adverse Event Reporting System (VAERS) reports of adverse events following hepatitis B vaccination from 2005 through 2015. During that time, 20,231 reports following hepatitis B or hepatitis B-containing vaccines, were submitted to VAERS. Over half of reports were in persons younger than 2 years of age; the majority of reports (78%) were following hepatitis B-containing vaccines in combination with other vaccines at the same visit. The most frequently reported adverse events for vaccines given in combination were fever, injection site redness, and vomiting. This review of the hepatitis B vaccine did not detect any new or unexpected safety concerns. These findings are consistent with pre-licensure clinical trials and other post-licensure monitoring and research.

  Source: Safety of currently licensed hepatitis B surface antigen vaccines in the United Stated, Vaccine Adverse Event Reporting System (VAERS), 2005-2015 [Vaccine. 2018]
- A separate review of VAERS studied reports made following the administration of hepatitis A (inactivated) and hepatitis B (recombinant) vaccines combined from May 2001 to September 2003. There were no unexpected health problems.

  Source: Adverse events after hepatitis A B combination vaccine [Vaccine. 2006]
- In the early 1990s, CDC conducted a study of healthy full-term newborns to determine whether hepatitis B vaccination of newborns increases the risk of fever and/or suspected sepsis. The study found no evidence of increased fevers, sepsis evaluations, allergy or brain problems or medical procedures after to newborn hepatitis B vaccination.

  Source: Safety of Neonatal hepatitis B vaccine administration [Pediatr Infect Dis J. 2001]
- In a 4-year case series review of hepatitis B vaccine reports among newborns, there were no serious health problems linked to the hepatitis B vaccine. This was the largest case series review of hepatitis B vaccination reports among newborn babies and infants. Several studies have evaluated a possible link between hepatitis B vaccination and multiple sclerosis or optic neuritis. The studies did not show any link.

Source: Safety of Neonatal Hepatitis B Vaccine Administration [Pediatr Infect Dis J. 2001]

Which adverse events are considered "serious?"

By the Code of Federal Regulations (CFR) Title 21, an adverse event is defined as serious if it involves any of the following outcomes:

- Death
- A life-threatening adverse event
- A persistent or significant disability or incapacity
- A congenital anomaly or birth defect
- Hospitalization, or prolongation of existing hospitalization

Learn more about adverse events.

CDC Monitors Vaccine Safety

CDC and FDA monitor the safety of vaccines after they are approved. If a problem is found with a vaccine, CDC and FDA will inform health officials, health care providers, and the public.

Related Scientific Articles

2015 to Present

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Prior to 2005

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