



Vaccine Safety

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Hepatitis A Vaccines

Safety Information

About Hepatitis A

Hepatitis A is a highly contagious liver infection caused by the hepatitis A virus. It can range from a mild illness lasting a few weeks to a severe illness lasting several months. Although rare, hepatitis A can cause death in some people. Hepatitis A usually spreads when a person unknowingly ingests the virus from food, drinks, or objects contaminated by stool (poop) from an infected person. Hepatitis A can also spread from close personal contact with an infected person such as through sex or caring for someone who is ill.

Most adults with hepatitis A have symptoms that include fatigue, loss of appetite, stomach pain, nausea, and jaundice (skin becomes yellow). It usually resolves within 2 months of infection. Most children younger than 6 years of age do not have symptoms or have an unrecognized infection.

[Learn more about hepatitis A.](#)

There are safe and effective vaccines than can protect against hepatitis A.

Vaccine Information Statements

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

[Hepatitis A](#)

Hepatitis A vaccine

Available Vaccines

There are 3 hepatitis A vaccines approved for use in the United States: 2 single antigen vaccines and 1 combination vaccine.

Who Should Get Hepatitis A Vaccine

CDC recommends 2 doses of hepatitis A vaccine, given at least 6 months apart for:

- All children, beginning at 1 year
- People with unstable housing or experiencing homelessness
- People who are at increased risk for infection
- People who are at increased risk for complications from hepatitis A

Talk with your
healthcare provider
about vaccines.

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

- Anyone who wants protection against hepatitis A

For more information, see [Who should get vaccinated against hepatitis A](#).



[Child and Adult Immunization Schedules](#)

Get CDC’s official recommended immunization schedules for children, adolescents, and adults.

Manufacturer Package Inserts

Single antigen hepatitis A vaccines



This shot contains only hepatitis A vaccine.

- **Havrix** [PDF – 16 pages] [↗](#) : The Food and Drug Administration (FDA) approved this vaccine in 1995. It is approved for people 1 year of age and older, travelers to other countries, and others at risk.
- **Vaqta** [PDF – 18 pages] [↗](#) : FDA approved this vaccine in 1996. It is approved for people 1 year of age and older, travelers to other countries, and others at risk.

Combination vaccine with hepatitis A



This shot contains hepatitis A vaccine and hepatitis B vaccine, combined into a single dose.

- **Twinrix** [PDF – 14 pages] [↗](#) : FDA approved this vaccine in 2001 for protection against hepatitis A and [hepatitis B](#) disease. It is approved for people 18 years of age and older, travelers to other countries, and others at risk.

Common Side Effects

Hepatitis A vaccines are safe and effective at preventing hepatitis A infections. Vaccines, like any medicine, can have side effects. The common side effects are usually mild and last 1-2 days.



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.

Hepatitis A Vaccines

Common Side Effects

- Swelling, tenderness, redness, warmth, or a hard lump where the shot was given
- Low fever
- General ill feeling
- Nausea
- Loss of appetite
- Headache

Who Should Not Get Hepatitis A Vaccine

Tell your vaccine provider if the person getting the vaccine:

- Has had an allergic reaction after a previous dose or any component of the hepatitis A vaccine
- Has had an allergic reaction to
 - Neomycin
 - Yeast (contraindication for Twinrix)

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 A vaccine.

More information [about contraindications and precautions](#).

More Information

[Hepatitis A Questions and Answers for the Public](#)

Learn more about the hepatitis A 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 A Vaccine – ACIP Recommendations and Guidance](#)

Official guidance on hepatitis A vaccine from the Advisory Committee on Immunization Practices (ACIP).

[Hepatitis A Questions and Answers for Healthcare Professionals](#)

Learn more about the hepatitis A virus, vaccination, and treatment.

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

Findings from vaccine safety monitoring systems and scientific studies have shown that hepatitis A vaccines have a favorable safety profile—the body of scientific evidence overwhelmingly supports their safety.


- Since hepatitis A vaccine was licensed in 1995 through 2005, approximately 50 million doses were distributed in the United States. In that same time, VAERS received 6,136 reports of adverse events among people who received the hepatitis A vaccine (by itself or with other vaccines). The most common events reported were fever, injection site reaction, rash, and headache. The review of these reports was unable to determine a causal relationship between the vaccine and the reported events. The review of VAERS reports were similar to the original safety review for Havrix and Vaqta. During prelicensure clinical trials, the most commonly reported side effects for Havrix and Vaqta in both adults and children included injection site reactions, such as soreness, tenderness, pain, warmth, and headache. Children 11-25 months who received Havrix were also reported to experience irritability, drowsiness, and loss of appetite.

Source: [Prevention of Hepatitis A Through Active or Passive Immunization: Recommendations of the Advisory Committee on Immunization Practices. \[MMWR. 2006\]](#)


- A 2004 study of Vaqta among a large group of California patients showed no health problems linked to vaccination. More than 49,000 doses of Hepatitis A vaccine were given to the patients; 15,000 were given to children younger than 18 years of age.

Source: [A Post-Licensure Evaluation of the Safety of Inactivated Hepatitis A Vaccine \(VAQTA, Merck\) in Children and Adults. \[Vaccine. 2004\]](#) 

- A 2-year review of Hepatitis A vaccine safety using VAERS data found no safety problems when the vaccine began to be used as part of the routine immunization schedule in the United States.

Source: [Two-year Review of Hepatitis A Vaccine Safety: Data from the Vaccine Adverse Event Reporting System \(VAERS\). \[Vaccine. 1998\]](#) 

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](#).

How CDC Monitors Vaccine Safety

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

CDC uses 3 systems to monitor vaccine safety:

- The [Vaccine Adverse Event Reporting System \(VAERS\)](#): an early warning system, co-managed by CDC and FDA, to monitor for potential vaccine safety problems. Anyone can report possible vaccine side effects to VAERS.

- The [Vaccine Safety Datalink \(VSD\)](#): a collaboration between CDC and 13 healthcare organizations that conducts vaccine safety monitoring and research.
- The [Clinical Immunization Safety Assessment \(CISA\) Project](#): a partnership between CDC and several medical research centers that provides expert consultation and conducts clinical research on vaccine-associated health risks.

Related Scientific Articles

Moro PL, Museru O, Niu M, Lewis P, Broder K. [Reports to the Vaccine Adverse Event Reporting System After Hepatitis A and Hepatitis AB Vaccines in Pregnant Women](#). [↗](#) *Am J, Obstet Gynecol*. 2014 Jun;210(6): 561.e1-6.

Karali Z, Basaranoglu ST, Karali Y, Oral B, Kilic SS. [Autoimmunity and hepatitis A vaccine in children](#) [↗](#). *J Investig Allergol Clin Immuno*. 2011;21(5):389-93.

Fiore AE, Wasley A, Bell BP. [Prevention of Hepatitis A Through Active or Passive Immunization: Recommendations of the Advisory Committee on Immunization Practices \(ACIP\)](#). *MMWR Recomm and Reps*. 2006 May 16;55(RR07):1-23.

Woo EJ, Miller NB, Ball R, VAERS Working Group. [Adverse events after hepatitis A B combination vaccine](#) [↗](#). *Vaccine*. 2006 Mar 24;24(14):2685-91.

Black S, Shinefield H, Hansen J, Lewis E, Su L, Coplan P. [A post-licensure evaluation of the safety of inactivated hepatitis A vaccine \(VAQTA, Merck\) in children and adults](#) [↗](#). *Vaccine*. 2004 Jan 26;22(5-6):766-72.

Niu MT, Salive M, Kruger C, Ellenberg SS. [Two-year review of hepatitis A vaccine safety: Data from the Vaccine Adverse Event Reporting System \(VAERS\)](#) [↗](#). *Clin Infect Dis*. 1998 Jun;26(6):1475-6.

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