Package Leaflet: Information for the user

Ambirix, suspension for injection in pre-filled syringe
Hepatitis A (inactivated) and hepatitis B (rDNA) (HAB) vaccine (adsorbed)

Read all of this leaflet carefully before you/your child starts receiving this vaccine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- This vaccine has been prescribed for you/your child only. Do not pass it on to others.
- If you/your child gets any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

This leaflet has been written assuming the person receiving the vaccine is reading it, but it can be given to adolescents and children so you may be reading it for your child.

What is in this leaflet

1. What Ambirix is and what it is used for

Ambirix is a vaccine used in infants, children and young people from 1 year up to and including 15 years. It is used to prevent two diseases: hepatitis A and hepatitis B.

- **Hepatitis A:** Infection with the hepatitis A virus may cause the liver to become swollen (inflamed). The virus is usually caught from food or drink that contains the virus. However, it is sometimes caught in other ways, such as by swimming in water that has sewage in it or from another infected person. The virus is found in body fluids such as faeces, serum or saliva.
  Symptoms begin 3 to 6 weeks after infection. Some people can feel sick, have a fever and aches and pains. After a few days they may be very tired, and have dark urine, pale faeces, yellowish skin or eyes (jaundice). The severity and type of symptoms can vary. Young children may not get all symptoms. Most children recover completely but the illness is usually severe enough to make children ill for about a month.

- **Hepatitis B:** Infection with the hepatitis B virus may cause the liver to become swollen (inflamed). The virus is usually caught from another infected person. It is found in body fluids such as blood, semen, vaginal secretions, or saliva (spit).
  Symptoms may not be seen for 6 weeks to 6 months after infection. Not always people who have been infected look or feel ill. Some people can feel sick, have a fever and aches and pains. However, others can become very ill. They may be very tired, and have dark urine, pale faeces, yellowish skin or eyes (jaundice). Some people may need to go into hospital.

  Most adults fully recover from the disease, but some people (particularly children) who may not have had symptoms can remain infected. They are called hepatitis B “carriers” and can still infect other people throughout their lives. Carriers are also at risk of serious liver problems, such as scarring (cirrhosis) or liver cancer.

How Ambirix works

- Ambirix helps the body to produce its own protection (antibodies) against these diseases. The vaccine does not contain live virus (see section 6 for the content of the vaccine) and therefore cannot cause hepatitis A or B infections.

- As with all vaccines, some people respond less well to a vaccine than others.

- Ambirix may not protect you from being ill if you have already caught the hepatitis A or B virus.

- Ambirix can only help to protect you against infections with hepatitis A or B viruses. It cannot protect against other infections that can affect the liver – even though these infections might have signs similar to those caused by the hepatitis A or B virus.

2. What you need to know before you receive Ambirix

Ambirix should not be given if:

- you are allergic to Ambirix, or any of the other ingredients of this vaccine (listed in section 6). Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of your face or tongue
- you have previously had an allergic reaction to any vaccine against hepatitis A or hepatitis B diseases
- you have a severe infection with a high temperature. The vaccine can be given after you have recovered. A minor infection such as a cold should not be a problem, but talk to your doctor first.

Ambirix should not be given if any of the above apply. If you are not sure, talk to your doctor, nurse or pharmacist before having Ambirix.

Warnings and precautions

Talk to your doctor, nurse or pharmacist before having Ambirix if:

- you need to be fully protected against hepatitis A and B infection within the next 6 months – your doctor may recommend a different vaccine
- you have a bleeding problem or bruise easily - the injection may be given just under the skin instead of into a muscle to reduce the amount of bleeding or bruising
- you have immune system problems (such as due to an illness, treatment or dialysis) - the vaccine may not work fully. This means you may not be protected against one or both of the hepatitis A and B viruses. Your doctor will run blood tests to see whether more injections are needed to help you be better protected
- you have fainted before or during a previous injection – in case this happens again. Fainting can occur (mostly in adolescents) following, or even before, any needle injection.

If any of the above apply (or you are not sure), talk to your doctor, nurse or pharmacist before having Ambirix.

Other medicines and Ambirix

Tell your doctor if you are taking, have recently taken or might take any other medicines or vaccines. This includes medicines obtained without a prescription and herbal medicines. Ask your doctor, nurse or pharmasist if you are not sure.

If you are taking medicines that affect your body's immune response, you can still have Ambirix if this is thought to be necessary. However, the vaccine may not work fully. This means that you may

not be protected against one or both of the hepatitis A and B viruses. Your doctor will run blood tests to see whether more injections are needed to help you be better protected.

Ambirix may need to be given at the same time as other vaccines for measles, mumps, rubella, diphtheria, tetanus, whooping cough (pertussis), poliomyelitis, *Haemophilus influenzae* type b or some types of treatments for hepatitis infections called "immunoglobulins". Your doctor will make sure that the vaccines are injected into different parts of your body.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think that you might be pregnant or are planning to have a baby, ask your doctor, nurse or pharmacist for advice before having this vaccine. Ambirix is not usually given to women who are pregnant or breast-feeding.

Driving and using machines

You may feel sleepy or dizzy after having Ambirix. If this happens, do not drive, cycle or use any tools or machines.

Ambirix contains neomycin and sodium

This vaccine contains neomycin (an antibiotic). Ambirix should not be given if you are allergic to neomycin.

This vaccine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How Ambirix is given

How the injection is given

- The doctor or nurse will give Ambirix as an injection into a muscle. This is usually into the upper arm.
- They will take care that Ambirix is not given into a vein.
- In very small children, the injection may be given into the thigh muscle.

How much is given

- You will normally have a total of two injections. Each is given on a separate visit.
- The injections will be given within 12 months:
  - The first injection – on a date agreed with your doctor.
  - The second injection – between 6 and 12 months after the first injection.

Your doctor will advise on the possible need for extra doses, and future booster dosing.

Missing a dose

- If you miss the second injection, talk to your doctor and arrange another visit as soon as possible.

- Make sure you finish the complete course of two injections. If not, you may not be protected against the diseases.

4. Possible side effects

Like all medicines, this vaccine can cause side effects, although not everybody gets them.

Serious side effects

- **Tell your doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:**allergic and anaphylactic reactions - the signs can include a rash that may be itchy or blistering, swelling of the eyes and face, difficulty in breathing or swallowing, a sudden drop in blood pressure and loss of consciousness.

Tell your doctor straight away if you notice any of the serious side effects listed above.

Side effects that occurred during clinical trials with Ambirix were as follows:

Very common (These may occur with more than 1 in 10 doses of the vaccine) :headache, loss of appetite, feeling tired or irritable, pain and redness where the injection was given.

Common (These may occur with up to 1 in 10 doses of the vaccine) :fever, feeling drowsy, stomach and digestive problems, swelling where the injection was given.

Additional side effects that have been reported during clinical trials with very similar combined hepatitis A and hepatitis B vaccines, include:

Common (These may occur with up to 1 in 10 doses of the vaccine) :generally feeling unwell, diarrhoea, feeling sick (nausea), reaction where the injection was given.

Uncommon (These may occur with up to 1 in 100 doses of the vaccine) : feeling dizzy, stomach pain, being sick (vomiting), upper airway infections, aching muscles (myalgia).

Rare (These may occur with up to 1 in 1,000 doses of the vaccine) :low blood pressure, joint pain (arthralgia), itching (pruritus), rash, pins and needles (paraesthesia), swollen glands in the neck, armpit or groin (lymphadenopathy), flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills.

Very rare (These may occur with up to 1 in 10,000 doses of the vaccine): hives (urticaria).

Please contact your doctor if you have similar side effects.

Side effects that occurred during routine use of Ambirix were as follows: fainting, loss of skin sensitivity to pain or touch (hypoaesthesia).

Additional side effects that occurred during routine use of very similar combined or individual hepatitis A and hepatitis B vaccines were as follows: multiple sclerosis, swelling of the spinal cord (myelitis), abnormal test results relating to the liver, swelling or infection of the brain (encephalitis), inflammation of some blood vessels (vasculitis), a degenerative disease of the brain (encephalopathy), swelling of the face, mouth and throat (angioneurotic oedema), severe headache with stiff neck and sensitivity to light (meningitis), a temporary inflammation of the nerves, causing pain, weakness and paralysis in the arms and legs and often progressing to the chest and face (Guillain-Barré syndrome). fits or seizures, inflammation of the nerves (neuritis), disease of the nerves of the eyes (optic neuritis), numbness or weakness of the arms and legs (neuropathy), immediate injection site pain, stinging and burning feeling, paralysis, drooping eyelid and sagging muscles on one side of the face (facial palsy), disease mainly affecting the joints with pain and swelling (arthritis), muscular weakness, purple or reddish-purple bumps on the skin (lichen planus), serious skin rashes (erythema multiforme), reduction in blood platelets, which increases risk of bleeding or bruising (thrombocytopenia), purple or red brown spots visible through the skin (thrombocytopenic purpura).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.You can also report side effects directly via the Yellow Card Scheme Website:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ambirix

Keep this vaccine out of the sight and reach of children.
Do not use this vaccine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
Store in a refrigerator (2°C to 8°C). Do not freeze. Freezing destroys the vaccine.
Store in the original package in order to protect from light.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ambirix contains

- The active substances are:

- Hepatitis A virus (inactivated) [1,2]	720 ELISA Units
- Hepatitis B surface antigen [3,4]	20 micrograms

[1]Produced on human diploid (MRC-5) cells
[2]Adsorbed on aluminium hydroxide, hydrated 0.05 milligrams Al^{3+}
[3]Produced in yeast cells (*Saccharomyces cerevisiae*) by recombinant DNA technology
[4]Adsorbed on aluminium phosphate, 0.4 milligrams Al^{3+}

- The other ingredients in Ambirix are: sodium chloride and water for injections.

What Ambirix looks like and contents of the pack

Ambirix is a white and slightly milky liquid.

Ambirix is available in 1-dose pre-filled syringe with or without separate needles, pack sizes of 1, 10, and 50.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

GlaxoSmithKline UK Limited
79 New Oxford Street
London
WC1A 1DG
United Kingdom

Manufacturer

GlaxoSmithKline Biologicals s.a.
Rue de l'Institut 89
B-1330 Rixensart
Belgium

Other formats:
To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only)
Please be ready to give the following information:
Product name **Ambirix, suspension for injection in pre-filled syringe**

Reference numbers 19494/0259

This is a service provided by the Royal National Institute of Blind People.

This leaflet was last revised in March 2025

The following information is intended for healthcare professionals only:

Upon storage, a fine white deposit with a clear colourless layer above may be observed.

The vaccine should be re-suspended before use. When re-suspended, the vaccine will have a uniform hazy white appearance.

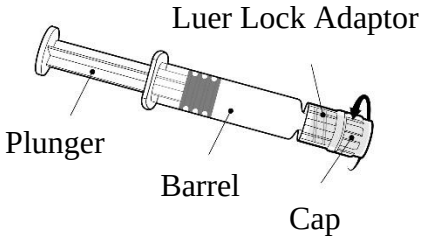
Re-suspension of the vaccine to obtain a uniform hazy white suspension

The vaccine should be re-suspended following the steps below.

1. Hold the syringe upright in a closed hand.
2. Shake the syringe by tipping it upside down and back again.
3. Repeat this action vigorously for at least 15 seconds.
4. Inspect the vaccine again:
    a. If the vaccine appears as a uniform hazy white suspension, it is ready to use – the appearance should not be clear.
    b. If the vaccine still does not appear as a uniform hazy white suspension - tip upside down and back again for at least another 15 seconds - then inspect again.

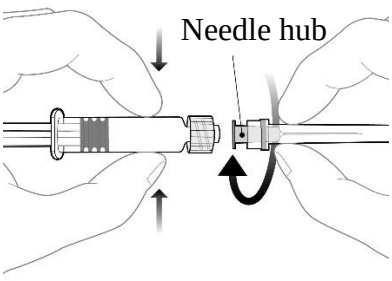
The vaccine should be inspected visually for any foreign particulate matter and/or abnormal physical appearance prior to administration. In the event of either being observed, do not administer the vaccine.

<u>Instructions for the pre-filled syringe</u>



Hold the syringe by the barrel, not by the plunger.

Unscrew the syringe cap by twisting it anticlockwise.



To attach the needle, connect the hub to the Luer Lock Adaptor and rotate a quarter turn clockwise until you feel it lock.

Do not pull the syringe plunger out of the barrel. If it happens, do not administer the vaccine.

Disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.